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Longitudinal Adherence to Long-Acting Cabotegravir plus Rilpivirine in Routine Clinical Practice: Updated Temporal Trends from the RELATIVITY Cohort in Spain

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Background

Long-acting cabotegravir plus rilpivirine (CAB+RPV LA) shifts adherence from daily self-administered tablets to scheduled healthcare-supported injections. Real-world evidence on schedule deviations, temporal patterns and their clinical consequences remains limited.

Objective

To characterize injection-schedule adherence, temporal patterns of late injections, associated factors and clinical outcomes after CAB+RPV LA initiation in routine Spanish HIV care.

Methods

Design and setting:

Nationwide, ambispective RELATIVITY cohort across 53 Spanish centers. Data cutoff: March 1, 2026.

Population and eligibility:

Virologically suppressed adults initiating CAB+RPV LA before December 31, 2024, without known compromising resistance.

Adherence and virological failure:

Adapted PDC with a ±7-day target window: complete (100%), high (90–99.9%) or suboptimal (<90%). VF: two HIV-1 RNA values ≥200 copies/mL, or one ≥500 leading to discontinuation.

Outcomes and statistical analysis:

Descriptive comparisons, univariable logistic regression for PDC <100%, adjusted models for late injections, Kaplan–Meier analyses and exploratory prediction with 5-fold cross-validation.

Results

Injection schedules were evaluable in 3,280/3,349 participants; 69 lacked sufficient data. Median PDC was 100.0% (IQR, 99.8–100.0). The PDC <90% group included 23 participants.

Adherence and temporal patterns

Complete adherence occurred in 2,309/3,280 (70.4%), high adherence in 948/3,280 (28.9%) and suboptimal adherence in 23/3,280 (0.7%): 99.3% had PDC ≥90%. At least one late injection was recorded in 1,254 participants (38.2%), including 436 (13.3%) with ≥2 late injections. The recorded percentage with ≥1 late injection per semester rose from 9.7% in semester 1 to 12.3% in semester 3, then declined. Temporal patterns are summarized by 6-month follow-up semester (Figure 1).

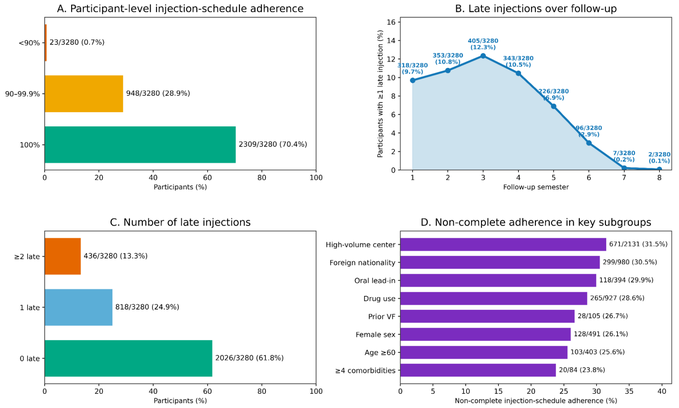


Figure 1. Injection-schedule adherence, semester patterns, late-injection counts and subgroup distributions.

Semester percentages use the full evaluable cohort (n=3,280).

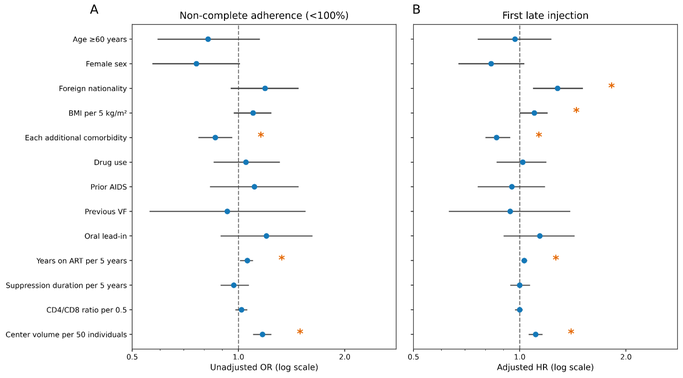
Table 1. Clinical outcomes by injection-schedule adherence

Outcome	PDC 100% (n=2,309)	PDC 90–99.9% (n=948)	PDC <90% (n=23)	P value
Participants, n	2,309	948	23	
HIV-1 RNA <50 copies/mL*	2,191/2,279 (96.1)	923/945 (97.7)	21/22 (95.5)	0.089
Definitive discontinuation	295/2,309 (12.8)	55/948 (5.8)	6/23 (26.1)	<0.001
Virological failure	27/2,309 (1.2)	1/948 (0.1)	0/23 (0.0)	0.010
Systemic AE discontinuation	46/2,309 (2.0)	6/948 (0.6)	0/23 (0.0)	0.016
ISR discontinuation	68/2,309 (2.9)	9/948 (0.9)	0/23 (0.0)	0.002
Other discontinuation	189/2,309 (8.2)	43/948 (4.5)	6/23 (26.1)	<0.001
Temporary interruption / oral bridging	25/2,309 (1.1)	32/948 (3.4)	1/23 (4.3)	<0.001

n/N (%) except participant counts. *Last available viral-load assessment. AE, adverse event; ISR, injection-site reaction. Comparisons are descriptive: adherence accrued during follow-up and the PDC <90% group included only 23 participants.

Factors associated with late injections

In adjusted Cox models, first late injection was associated with foreign nationality (aHR, 1.28; 95% CI, 1.09–1.51), BMI per 5 kg/m² (1.10; 1.00–1.20), prior ART per 5 years (1.03; 1.01–1.05) and center volume per 50 participants (1.11; 1.06–1.16). Each additional comorbidity was associated with a lower hazard (0.86; 0.80–0.94). Adjusted analyses of ≥2 late injections similarly identified center volume, prior ART exposure and comorbidity burden.



*P<.05.

Figure 2. Univariable ORs for PDC <100% (A) and adjusted HRs for first late injection (B).

Table 2. Adjusted determinants of ≥2 late injections

Predictor	Adjusted OR (95% CI)	P value
Age ≥60 years	0.68 (0.42–1.11)	0.119
Female sex	0.75 (0.50–1.13)	0.166
Foreign nationality	0.89 (0.65–1.21)	0.458
BMI per 5 kg/m²	1.07 (0.90–1.26)	0.459
Each additional comorbidity	0.82 (0.71–0.96)	0.015
Drug use	0.78 (0.57–1.07)	0.119
Prior AIDS	1.11 (0.74–1.66)	0.616
Previous VF	1.06 (0.53–2.11)	0.869
Oral lead-in	1.12 (0.73–1.70)	0.608
Prior ART per 5 years	1.07 (1.02–1.11)	0.003
Suppression per 5 years	0.95 (0.84–1.08)	0.419
CD4/CD8 ratio per 0.5	1.02 (0.98–1.07)	0.280
Center volume per 50 participants	1.23 (1.13–1.33)	<0.001

Multivariable logistic regression. Age <60 years is the reference.
OR, odds ratio; HR, hazard ratio; CI, confidence interval; ART, antiretroviral therapy.

Clinical outcomes and prediction

Virological failure was rare: 27/2,309 (1.2%) with PDC 100%, 1/948 (0.1%) with PDC 90–99.9%, and 0/23 with PDC <90%. The non-monotonic pattern does not establish a causal relationship with adherence. Viral suppression at the last assessment remained high: 21/22 (95.5%) with PDC <90% and 3,114/3,224 (96.6%) with PDC ≥90%.

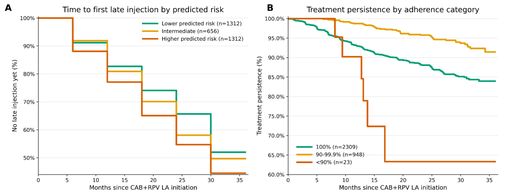


Figure 3. Time to first late injection by predicted risk (A) and persistence by final PDC category (B).

Descriptive analyses: final adherence categories accrue during follow-up and are related to treatment persistence.

Baseline prediction was weak: cross-validated AUC 0.53, average precision 0.32 and Brier score 0.23. Calibration overestimated risk

Conclusions

Injection-schedule adherence was high in routine care: 99.3% had PDC ≥90%, and suboptimal adherence was uncommon (0.7%).

Baseline characteristics did not support clinically useful adherence prediction. Findings favor reliable delivery systems and broadly applied operational support.

Virological failure was rare. Clinical and temporal comparisons require caution because adherence accrued during follow-up and the PDC <90% group was very small.

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