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Historical Genotype Availability and Outcomes After Switching to Long-Acting Cabotegravir Plus Rilpivirine: The RELATIVITY Cohort

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Background

The association between historical HIV genotype availability and virological failure after switching to long-acting cabotegravir plus rilpivirine (CAB+RPV LA) remains uncertain.

Objective

To evaluate the association of historical genotype availability with virological failure and treatment persistence after switching to CAB+RPV LA.

Methods

Design and setting:
Nationwide, ambispective observational study within the Spanish RELATIVITY cohort, including 53 centers. Data cutoff: March 1, 2026.

Population and eligibility:
Adults with HIV-1 RNA <50 copies/mL who initiated CAB+RPV LA by December 31, 2024, without known CAB/RPV-compromising resistance.

Definition of virological failure:
Two consecutive HIV-1 RNA measurements ≥200 copies/mL, or a single measurement ≥500 copies/mL leading to CAB+RPV LA discontinuation.

Outcomes and statistical analysis:
Time to virological failure and definitive discontinuation: Kaplan–Meier estimates and log-rank tests. Cox models adjusted for previous virological failure.

Results

Among 3,349 participants, genotype status was evaluable in 3,235: available in 1,540 (47.6%) and unavailable in 1,695 (52.4%). Status was missing in 114 participants. The time-to-event analysis included 3,227 participants.

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Main results

Virological failure occurred in 28/3,349 participants (0.8%). In the time-to-event population, 11/1,692 participants without and 17/1,535 with an available genotype experienced failure. At 36 months, cumulative failure was 0.98% (95% CI, 0.44–2.15%) without versus 1.25% (95% CI, 0.77–2.02%) with an available genotype (log-rank P=0.184). Treatment persistence was 86.19% versus 85.73%, respectively (log-rank P=0.100). Neither comparison detected a statistically significant association with genotype availability.

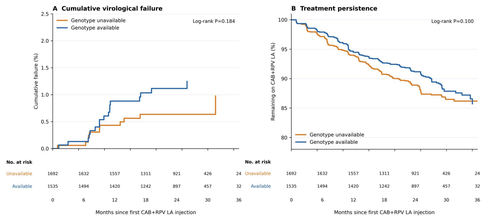


Figure 1. Cumulative virological failure and treatment persistence by historical genotype availability.

Characteristic	Unavailable (n=1,695)	Available (n=1,540)	OR (95% CI)	P value
Study population				
Participants, n/N (%)	1,695/3,235 (52.4)	1,540/3,235 (47.6)		
Demographics and anthropometry				
Age, years	46.0 [37.0-56.0]	45.0 [37.0-52.2]		<0.001
BMI, kg/m²	25.3 [23.1-28.0]	25.5 [23.4-28.2]		0.111
Female sex	279/1,689 (16.5)	207/1,536 (13.5)	0.79 (0.64-0.96)	0.018
Male sex	1,398/1,689 (82.8)	1,318/1,536 (85.8)	1.26 (1.04-1.53)	0.020
Sex not available	6/1,695 (0.4)	4/1,540 (0.3)	0.73 (0.21-2.60)	0.631
Nationality				
Foreign nationality	584/1,686 (34.6)	397/1,538 (25.8)	0.66 (0.56-0.77)	<0.001
Spanish nationality	1,102/1,686 (65.4)	1,141/1,538 (74.2)	1.52 (1.30-1.78)	<0.001
Nationality not available	9/1,695 (0.5)	2/1,540 (0.1)	0.24 (0.05-1.13)	0.071
HIV history and immune status				
Nadir CD4+ count, cells/mm³	328 [194-500]	344 [198-492]		0.457
Baseline CD4+ count, cells/mm³	804 [620-1,038]	788 [591-1,024]		0.179
Baseline CD4/CD8 ratio	1.01 [0.73-1.34]	0.95 [0.68-1.28]		<0.001
Previous virological failure	36/1,319 (2.7)	68/1,304 (5.2)	1.96 (1.30-2.96)	0.001
Previous VF status unavailable	376/1,695 (22.2)	236/1,540 (15.3)		
Prior AIDS diagnosis	212/1,498 (14.2)	193/1,447 (13.3)	0.93 (0.76-1.15)	0.556
Prior AIDS status unavailable	197/1,695 (11.6)	93/1,540 (6.0)		
Treatment history and switch characteristics				
Previous regimen documented	1,621/1,695 (95.6)	1,496/1,540 (97.1)		
Previous RPV-containing regimen	486/1,695 (28.7)	389/1,540 (25.3)		
Previous NNRTI-containing regimen	545/1,695 (32.2)	429/1,540 (27.9)		
Detailed ART/adherence/VF history*	1,143/1,695 (67.4)	Not applicable*		
ART duration before switch, years	10.0 [6.0-18.0]	9.0 [5.0-12.9]		<0.001
Virological suppression duration, months	96.0 [36.0-163.0]	72.0 [28.0-120.0]		<0.001
Oral lead-in	272/1,695 (16.0)	119/1,540 (7.7)	0.44 (0.35-0.55)	<0.001
Baseline INSTI-based ART	1,290/1,621 (79.6)	1,216/1,496 (81.3)	1.11 (0.93-1.33)	0.240
Baseline PI-based ART	59/1,621 (3.6)	99/1,496 (6.6)	1.88 (1.35-2.61)	<0.001
Substance use and psychiatric comorbidity				
Drug use	481/1,504 (32.0)	441/1,441 (30.6)	0.94 (0.80-1.10)	0.427
Drug use not available	191/1,695 (11.3)	99/1,540 (6.4)	0.54 (0.42-0.70)	<0.001
Psychiatric disorder	143/1,695 (8.4)	174/1,540 (11.3)	1.38 (1.09-1.76)	0.006
Alcoholism	134/1,695 (7.9)	186/1,540 (12.1)	1.60 (1.26-2.04)	<0.001

Median [IQR] or n/N (%). ORs use evaluable observations. Missing genotype status: 114/3,349 (3.4%).
*History field collected only when genotype was unavailable.

Table 1. Baseline characteristics by historical genotype availability

Historical and post-failure resistance

Among 1,540 participants with an available genotype, 1,319 (85.6%) had no historical RAMs detected. NRTI and NNRTI RAMs were each recorded in 123 (8.0%) and INSTI RAMs in 12 (0.8%).

No participant had known CAB/RPV-compromising resistance under the eligibility criteria. Median time to failure was 9.1 months (IQR, 7.0–13.2), with 20/28 events (71.4%) within 12 months. Post-failure genotyping was performed in all 28 cases. Substitutions were recorded in 19/28 (67.9%), including NNRTI entries in 14/28 (50.0%), INSTI entries in 16/28 (57.1%), and both in 11/28 (39.3%).

Table 2. Historical genotypic profile and resistance-associated mutations.

Historical genotype / resistance characteristic	n/N (%)
Genotype-availability status	
Historical genotypic study available	1,540/3,235 (47.6)
Historical genotypic study unavailable	1,695/3,235 (52.4)
Missing genotype-availability status	114/3,349 (3.4)
Subtype among participants with genotype	
Subtype B	688/1,540 (44.7)
Subtype A1/A2	34/1,540 (2.2)
Subtype F/CRF	46/1,540 (3.0)
Other subtype	66/1,540 (4.3)
Subtype not available	706/1,540 (45.8)
Historical resistance among participants with genotype	
Wild-type/no mutations detected	1,319/1,540 (85.6)
Any database-coded historical RAM	221/1,540 (14.4)
Any NRTI RAM	123/1,540 (8.0)
M184V	25/1,540 (1.6)
Any NNRTI RAM	123/1,540 (8.0)
K103N	48/1,540 (3.1)
E138A	13/1,540 (0.8)
Other	74/1,540 (4.8)
Any INSTI RAM	12/1,540 (0.8)
L74M/I/F	1/1,540 (0.1)
T97A	1/1,540 (0.1)
Other	10/1,540 (0.6)
Known CAB/RPV-compromising RAM*	0/1,540 (0.0)*
Number of database-coded RAM classes	
0 RAM classes detected	1,319/1,540 (85.6)
1 RAM class detected	184/1,540 (11.9)
2 RAM classes detected	37/1,540 (2.4)
3 RAM classes detected	0/1,540 (0.0)

RAM percentages use n=1,540 available genotypes. Classes are not mutually exclusive.
*Known compromising resistance was excluded. Historical reports do not exclude archived minority variants.

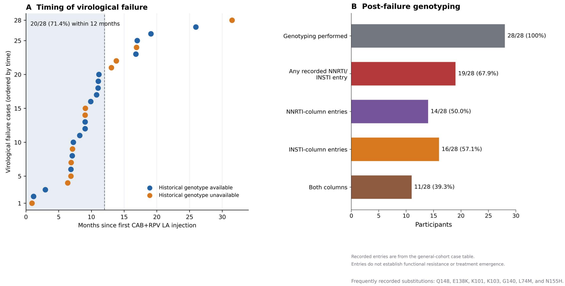


Figure 2. Timing of virological failure and post-failure resistance.

Adjusted analyses

Complete-case Cox models included 2,620 participants, with 26 virological failures and 263 definitive discontinuations. After adjustment for previous failure, genotype availability was not significantly associated with virological failure (adjusted HR, 1.82; 95% CI, 0.81–4.10; P=0.146) or definitive discontinuation (adjusted HR, 0.85; 95% CI, 0.66–1.08; P=0.177). Wide confidence intervals do not establish equivalence.

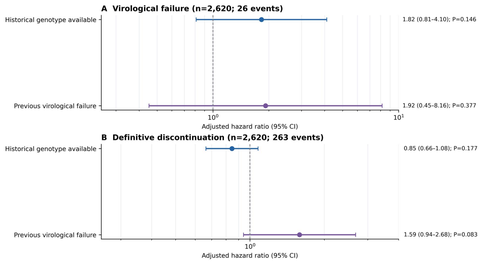


Figure 3. Adjusted associations with virological failure and definitive discontinuation.

Conclusions

In clinically selected, virologically suppressed individuals without known CAB/RPV-compromising resistance, genotype availability was not significantly associated with failure or persistence.

Historical genotypes should be reviewed whenever available. When unavailable, careful assessment of treatment and virological history remains essential.

Failure was rare, but resistance was frequent among evaluable post-failure genotypes. Wide confidence intervals preclude claims of equivalence.

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ClinicalTrials.gov: NCT07703748

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