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Long-Acting Cabotegravir plus Rilpivirine in People With HIV Aged ≥60 Years: Real-World Evidence From the RELATIVITY Cohort in the Context of Multimorbidity

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Background

Long-acting injectable cabotegravir plus rilpivirine (CAB+RPV LA) reduces dosing frequency and treatment complexity; however, older adults ≥60 years are underrepresented in clinical trials, and real-world evidence is limited.

Objective

Evaluate the effectiveness, safety, injection schedule coverage, and persistence of CAB+RPV LA in adults aged ≥60 years in the real-world RELATIVITY cohort.

Methods

Design:

Multicenter retro-prospective observational study (RELATIVITY cohort, Spain).

Population:

Among 3,349 participants in the RELATIVITY cohort, 407 (12.2%) were aged ≥60 years.

Definition of virological failure:

Two consecutive HIV-1 RNA measurements ≥200 copies/mL, or one measurement ≥500 copies/mL leading to treatment discontinuation.

Analysis:

Time to definitive discontinuation was estimated using Kaplan–Meier methods and compared with the log-rank test. Multivariable Cox models evaluated age ≥60 years and comorbidity burden in relation to discontinuation, adjusting for sex, BMI, prior AIDS, previous virological failure, and drug use. Exploratory analyses included age-stratified models and an age-by-comorbidity interaction.

Results

A total of 3349 participants with available age data were included in the age-stratified analysis, of whom 2942 (87.8%) were aged <60 years and 407 (12.2%) were aged ≥ 60 years. Older participants had a median age of 63.0 years (interquartile range, 61.0–66.8) compared with 43.0 years (interquartile range, 36.0–51.0) among those aged <60 years. Women were more frequent among older participants (21.2% vs. 14.1%; OR, 1.64; 95% CI, 1.26–2.13; P<0.001), and Spanish nationality was markedly more common (90.7% vs. 66.9%; OR, 4.80; 95% CI, 3.40–6.76; P<0.001). Main characteristics are described in Table 1.

P-1033

Virological and immunological outcomes

Observed virological effectiveness remained high and comparable between age groups. At the last assessment, virological suppression was 96.5% in participants aged <60 years and 97.3% in those aged ≥60 years (P=0.556), with rare virological failure (0.9% vs 0.2%; P=0.244).

At month 23, CD4+ counts remained stable, while the CD4/CD8 ratio improved in both groups (≥60 years: 0.92 to 1.05; P<0.001).

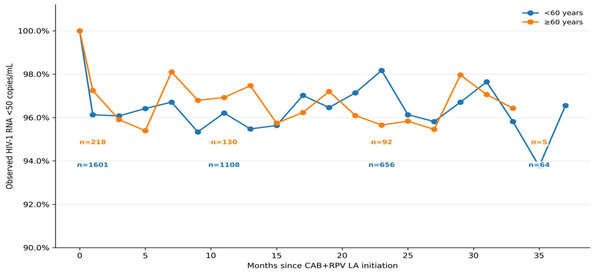


Figure 1. Observed virological suppression during routine follow-up. n denotes participants with available viral-load data. No imputation.

Variable/statistic	<60 years	≥60 years	OR (95% CI)	P value
Participants, n/N (%)	2942/3349 (87.8)	407/3349 (12.2)		
Baseline age, years	43.0 [36.0-51.0]	63.0 [61.0-66.8]		<0.001
Body mass index, kg/m²	25.3 [23.2-28.0]	25.9 [23.5-28.6]		0.016
Sex				<0.001
Female	413/2933 (14.1)	86/406 (21.2)	1.64 (1.26-2.13)	
Male	2498/2933 (85.2)	319/406 (78.6)	0.64 (0.49-0.83)	
Transgender female	22/2933 (0.8)	1/406 (0.2)	0.33 (0.04-2.43)	
Nationality				<0.001
Spanish	1962/2931 (66.9)	369/407 (90.7)	4.80 (3.40-6.76)	
Foreigner	969/2931 (33.1)	38/407 (9.3)	0.21 (0.15-0.29)	
Number of comorbidities	0 [0-1]	2 [1-3]		<0.001
0-1 comorbidities	2567/2942 (87.3)	190/407 (46.7)	0.13 (0.10-0.16)	<0.001
2-3 comorbidities	336/2942 (11.4)	171/407 (42.0)	5.62 (4.48-7.05)	<0.001
≥4 comorbidities	39/2942 (1.3)	46/407 (11.3)	9.48 (6.11-14.73)	<0.001
Type of Comorbidities				
Hypertension	259/2942 (8.8)	152/407 (37.3)	6.17 (4.87-7.83)	<0.001
Diabetes mellitus	99/2942 (3.4)	60/407 (14.7)	4.97 (3.54-6.97)	<0.001
Dyslipidemia	549/2942 (18.7)	206/407 (50.6)	4.47 (3.60-5.54)	<0.001
Ischemic heart disease	29/2942 (1.0)	25/407 (6.1)	6.57 (3.81-11.34)	<0.001
Cerebrovascular disease	17/2942 (0.6)	15/407 (3.7)	6.58 (3.26-13.29)	<0.001
Peripheral vascular disease	14/2942 (0.5)	6/407 (1.5)	3.13 (1.20-8.19)	0.014
Chronic kidney disease	32/2942 (1.1)	33/407 (8.1)	8.02 (4.88-13.20)	<0.001
Osteopenia/osteoporosis	97/2942 (3.3)	54/407 (13.3)	4.49 (3.16-6.37)	<0.001
Chronic lung disease	73/2942 (2.5)	39/407 (9.6)	4.17 (2.78-6.24)	<0.001
Psychiatric disorder	273/2942 (9.3)	49/407 (12.0)	1.34 (0.97-1.85)	0.077
Active oncologic disease	19/2942 (0.6)	8/407 (2.0)	3.08 (1.34-7.09)	0.005
Alcoholic liver disease	7/2942 (0.2)	7/407 (1.7)	7.34 (2.56-21.03)	<0.001
Chronic liver disease	64/2942 (2.2)	37/407 (9.1)	4.50 (2.96-6.84)	<0.001
Non-alcoholic fatty liver disease	67/2942 (2.3)	17/407 (4.2)	1.87 (1.09-3.22)	0.022
Active hepatitis C	34/2942 (1.2)	7/407 (1.7)	1.50 (0.66-3.40)	0.332
Active hepatitis B (HBsAg+)	4/2942 (0.1)	1/407 (0.2)	1.81 (0.20-16.23)	0.477
Lifestyle factors				
Drug use	856/2675 (32.0)	87/376 (23.1)	0.64 (0.50-0.82)	<0.001
Smoking	861/2942 (29.3)	115/407 (28.3)	0.95 (0.76-1.20)	0.674
Alcohol use disorder	301/2942 (10.2)	22/407 (5.4)	0.50 (0.32-0.78)	0.002
Chemsex	92/2942 (3.1)	2/407 (0.5)	0.15 (0.04-0.62)	0.001
Other drugs	160/2942 (5.4)	14/407 (3.4)	0.62 (0.36-1.08)	0.089

Table 1. Baseline demographic characteristics, comorbidities, and lifestyle factors according to baseline age groups

Safety outcomes

Safety-related discontinuations were uncommon, with no statistically significant differences between age groups.

Among respondents at month 23, injection-related pain interfering with daily activities or considered intolerable was uncommon (0.0% in participants aged ≥60 years vs 1.7% in those aged <60 years; P=0.162). Nearly all respondents reported that treatment benefits outweighed injection-related discomfort (99.4% vs 99.2%, respectively).

Persistence, injection-schedule coverage, and discontinuation

The median follow-up was similar between the groups (25.8 [21.0–30.1] months in older participants vs. 25.1 [19.3–30.8] months in younger participants; P=0.176). Treatment continuation at the end of follow-up was virtually identical: 353 of 407 older adults (86.7%) and 2555 of 2942 younger adults (86.8%) remained on CAB+RPV LA.

Definitive discontinuation occurred in 46 older (11.3%) and 324 younger participants (11.0%). Kaplan–Meier estimates showed overlapping persistence curves, with no differences by age group (log-rank P=0.930; Figure 2).

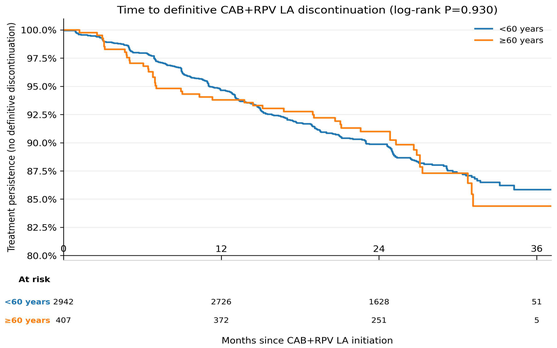


Figure 2. Kaplan–Meier treatment persistence curves

No statistically significant differences were observed in discontinuation due to systemic adverse events (2.7% vs. 1.5%; OR, 1.87; 95% CI, 0.86–3.73; P=0.088), injection-site reactions (2.9% vs. 2.3%; OR, 1.30; 95% CI, 0.64–2.46; P=0.384), virological failure (0.2% vs. 0.9%; OR, 0.27; 95% CI, 0.01–1.62; P=0.244), or other reasons (6.6% vs. 7.5%; OR, 0.87; 95% CI, 0.56–1.33; P=0.613).

Injection-schedule coverage was high in both age groups, with ≥90% coverage in 401/403 participants aged ≥60 years (99.5%) and 2856/2877 aged <60 years (99.3%).

Complete (100%) coverage was observed in 74.4% and 69.8%, respectively, while suboptimal coverage (<90%) was uncommon (0.5% vs 0.7%).

The distribution across the three coverage categories (100%, 90–99.9%, and <90%) did not differ significantly between age groups (global P=0.158).

Multivariable analysis

In the multivariable Cox model (2873 participants; 322 discontinuations), age ≥60 years was not associated with definitive discontinuation (aHR, 0.93; 95% CI, 0.65–1.33; P=0.710), nor was comorbidity burden (aHR per additional comorbidity, 0.98; P=0.733). Female sex was independently associated with a higher risk of discontinuation (aHR, 1.57; 95% CI, 1.19–2.06; P=0.001).

Comorbidity burden, discontinuation, and virological failure according to age group

Exploratory analyses suggested that comorbidity burden was associated with treatment persistence differently by age. Among participants aged ≥60 years, definitive discontinuation increased from 7.9% with 0–1 comorbidities to 19.6% with ≥4, with each additional comorbidity independently associated with higher discontinuation risk (aHR, 1.26; 95% CI, 1.02–1.56; P=0.034).

The age-by-comorbidity interaction was significant (P=0.020). Discontinuations for non-virological reasons increased numerically with comorbidity burden, although no individual reason reached statistical significance. Virological failure remained rare (Figure 3).

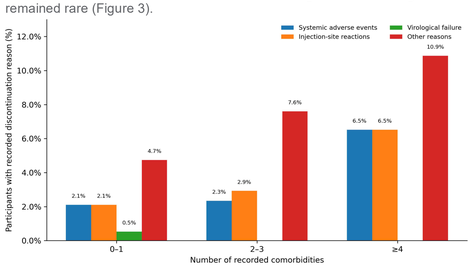


Figure 3. Analysis-classified reasons for discontinuation by comorbidity burden among participants aged ≥60 years Percentages use all participants in each stratum: n=190, 171, and 46, respectively. Reasons were not mutually exclusive.

Conclusions

- CAB+RPV LA maintained high effectiveness, persistence, injection-schedule coverage, and safety in PWH aged ≥60 years.
- Age ≥60 years was not associated with discontinuation, although higher comorbidity burden may identify individuals needing closer follow-up.
- Long-acting ART should be considered a valuable option in older adults with HIV rather than avoided because of age alone.

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