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02C. Tx Strategies: Real-world & implementation science studies, oral & injectable therapy

EXPLORE RELATIVITY

96-week effectiveness and tolerability of long-acting injectable cabotegravir plus rilpivirine in young adults with perinatally acquired HIV: a substudy of the RELATIVITY cohort

Alejandro de Gea Grela[1], Noemi Cabello[2], María José Galindo[3], Jesús Troya[4], Rosa María Martínez Álvarez[5], María Remedios Alemán[6], María de Lagarde[7], Miguel Torralba[8], Luis Buzón[9], María José Crusells[10], Francisco Fanjul[11], Adrián Rodríguez[12], Raúl Parra Fariñas[13], Mireia Cairó[14], María del Carmen Navarro[15], Ignacio De los Santos[16], Carmen Hidalgo[17], Luis Enrique Morano[18], Enrique Bernal[19], David Vinuesa[20], María Josefa de la Asunción[21], Lucia Fito[22], Hadrián Pernas[23], María Jesús Vivancos[24], José Ignacio Bernardino[1], on behalf of the RELATIVITY Cohort Study Group

Background

- Adults with **perinatally acquired HIV (PaHIV)** have lifelong antiretroviral therapy (ART) exposure.
- Previous virological failure and **archived resistance** are frequent in this group.
- Real-world data on **long-acting injectable (LAI) cabotegravir plus rilpivirine (CAB+RPV)** in PaHIV are scarce.

Objective

To describe **virological outcomes** and **treatment persistence** after switching to LAI CAB+RPV in adults with PaHIV, compared with adults without documented perinatal acquisition.

Methods

- **Design:** ambispective, multicentre study nested in the RELATIVITY cohort (58 Spanish hospitals). All participants were suppressed at LAI CAB+RPV initiation.
- **Primary comparison:** 1:1 propensity-score matching on age, sex, nationality and baseline CD4+ **(Figure 1)**.
- **Outcomes:** HIV-1 RNA ≥50 copies/mL, temporary interruption and definitive discontinuation.
- **Analysis:** Fisher or Mann–Whitney U tests (full cohort); exact McNemar or Wilcoxon signed-rank tests (matched pairs); exact 95% CIs.

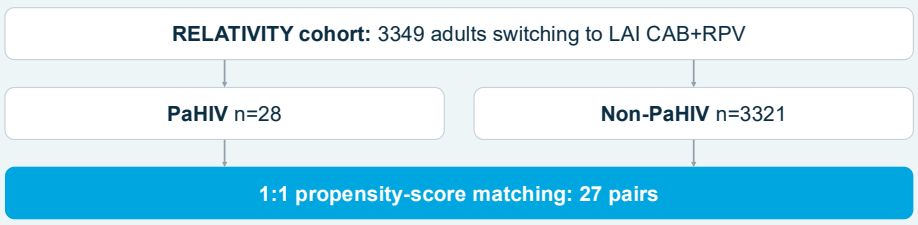

Figure 1. Study population.

Results

Full cohort **Table 1. Baseline characteristics (28 PaHIV vs 3321 non-PaHIV)**

Characteristic	PaHIV (n=28)	Non-PaHIV (n=3321)	p
Demographic characteristics			
Age, years	26.8 (23.0–32.0)	45.4 (37.0–54.4)	**<0.001**
Female sex	17/28 (60.7%)	482/3311 (14.6%)	**<0.001**
Spanish nationality	23/28 (82.1%)	2308/3310 (69.7%)	0.214
Clinical and immunovirological profile			
CD4+ nadir, cells/mm³	316 (291–568)	339 (197–498.8)	0.664
Baseline CD4+, cells/mm³	853 (528–1050)	797 (602.8–1030)	0.963
Years on ART before LAI CAB+RPV	23.0 (17.5–27.0)	9.0 (5.0–15.0)	**<0.001**
First to last injection, months	23.7 (16.6–27.0)	25.1 (19.3–30.8)	0.153
Historical virological profile and resistance			
Previous virological failure to any ART	6/25 (24.0%)	102/2681 (3.8%)	**<0.001**
NRTI resistance mutations	8/17 (47.1%)	115/1523 (7.6%)	**<0.001**
NNRTI resistance mutations	5/17 (29.4%)	118/1523 (7.7%)	**0.008**
>3 blips, look-back ≤5 years	4/26 (15.4%)	62/3047 (2.0%)	**0.002**

Median (IQR) or n/N (%). Denominators exclude missing values. Fisher's exact or Mann–Whitney U test; p in bold if <0.05. Resistance among participants with an available genotype. ART, antiretroviral therapy; NRTI/NNRTI, nucleoside/non-nucleoside reverse transcriptase inhibitor.

Full cohort. Virological failure: 1/28 PaHIV (3.6%) vs 27/3321 non-PaHIV (0.8%; p=0.210). **Definitive discontinuation:** 7/28 (25.0%) vs 363/3321 (10.9%; p=0.029); six of the seven in PaHIV were non-virological **(Figure 2)**. Latest HIV-1 RNA <50 copies/mL in 26/28 PaHIV, including all 21 without definitive discontinuation.

Propensity-score matched (1:1) **Table 2. Baseline characteristics (27 pairs)**

Characteristic	PaHIV (n=27)	Non-PaHIV (n=27)	|SMD| or p
Matching variables (|SMD|)			
Age, years	27.0 (23.0–32.0)	26.0 (24.0–30.0)	0.03
Female sex	17/27 (63.0%)	12/27 (44.4%)	0.37
Spanish nationality	23/27 (85.2%)	19/27 (70.4%)	0.38
Baseline CD4+, cells/mm³	853 (528–1050)	709 (559.5–912)	0.21
Treatment history (paired p)			
Years on ART before LAI CAB+RPV	25.0 (19.0–27.0)	4.0 (2.0–6.0)	**<0.001**
Months suppressed before LAI	92.5 (9.5–158.2)	24.0 (18.0–48.0)	**<0.001**
Previous virological failure	6/24 (25.0%)	1/22 (4.5%)	0.219

Median (IQR) or n/N (%). |SMD|, absolute standardized mean difference. Paired p: exact Wilcoxon signed-rank or McNemar test.

Propensity-score matched (1:1). Virological failure: 1/27 in each group (p=1.000). **Definitive discontinuation:** 7/27 (25.9%) vs 5/27 (18.5%; p=0.774) **(Figure 3)**. Sensitivity analyses with 1:2, 1:3 and 1:4 matching showed consistent findings.

Timing of discontinuations in PaHIV

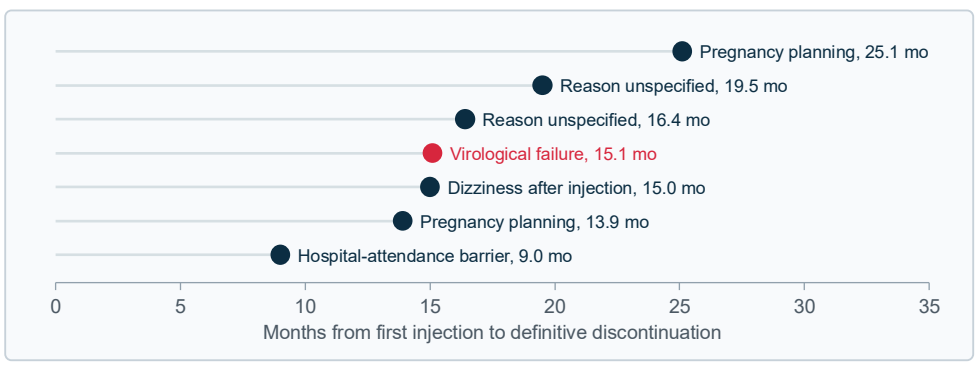

Figure 2. Each point is one of the 7 definitive discontinuations, with the recorded reason. Six were non-virological. Red: virological failure.

Propensity-score matched outcomes (1:1)

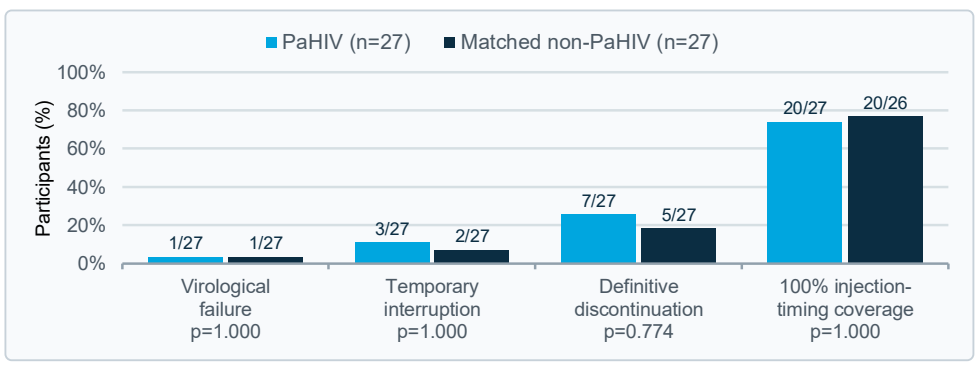

Figure 3. Outcomes in the 27 matched pairs. Bar labels show n/N. Exact McNemar test.

Conclusions

- Recorded **virological failure was uncommon** in suppressed adults with PaHIV who switched to LAI CAB+RPV.
- **Definitive discontinuation was numerically more frequent** than in matched controls, mostly for non-virological reasons.
- In the matched analysis, there were **no statistically significant differences** in outcomes between groups.
- Small sample, sparse events and residual imbalance **preclude claims of equivalence**. Persistence should be monitored as a distinct outcome.

Affiliations (all in Spain): [1]Hospital Universitario la Paz, Madrid. [2]Hospital Clínico San Carlos, Madrid. [3]Hospital Clínico Universitario, Valencia. [4]Hospital Universitario Infanta Leonor, Madrid. [5]Hospital Universitario Miguel Servet, Zaragoza. [6]Hospital Universitario de Canarias, Tenerife. [7]Hospital 12 de Octubre, Madrid. [8]Hospital Universitario de Guadalajara, Guadalajara. [9]Hospital Universitario de Burgos, Burgos. [10]Hospital Universitario Lozano Blesa, Zaragoza. [11]Hospital Universitari Son Espases, Palma de Mallorca. [12]Hospital Universitari Son Llatzer, Palma de Mallorca. [13]Hospital Universitario Marqués de Valdecilla, Santander. [14]Hospital Universitario Mutua de Terrassa, Terrassa. [15]Hospital Universitario Parc Taulí, Sabadell. [16]Hospital Universitario la Princesa, Madrid. [17]Hospital Universitario Virgen de las Nieves, Granada. [18]Hospital Universitario Álvaro Cunqueiro, Vigo. [19]Hospital General Universitario Reina Sofía, Murcia. [20]Hospital Clínico San Cecilio, Granada. [21]Hospital de Denia Marina Salud, Denia. [22]Hospital Universitario de Torrejón, Torrejón de Ardoz. [23]Complejo Hospitalario Universitario de Pontevedra, Pontevedra. [24]Hospital Universitario Ramón y Cajal, Madrid.

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Contact: Alejandro de Gea Grela, alejandro.degea@salud.madrid.org

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