



Long-acting injectable cabotegravir and rilpivirine outcomes in HIV-positive migrants in Spain: do they have worse outcomes?

Jara Llenas-García¹; Roberto Pedrero Tome²; Luis Ramos Ruperto³; María José Galindo Puerto⁴; Mariano Matarranz del Amo⁵; Carolina Navarro⁶; Miguel Torralba⁷; Mireia Santacreu⁸; María Aguilera García⁹; Alfonso Cabello Úbeda¹⁰; Isabel San Joaquín Conde¹¹; Luis Enrique Morano¹²; Noemí Cabello-Clotet¹³; Patricia Martín Rico¹⁴; Carmen Montero Hernández¹⁵; Elisa Pino¹⁶; Alberto Díaz de Santiago¹⁷; Ruth Calderón Hernández¹⁸; Enrique Bernal¹⁹; María Jesús Vivancos Gallego²⁰; María Antonia Sepúlveda²¹; Chiara Fanciulli²²; Álvaro Cecilio²³; Josefa Soler González²⁴; Sergio Padilla²⁵; Juan Emilio Losa García²⁶; Carlos Armiñanzas Castillo²⁷; Antonio Jesús Sánchez Guirao²⁸; María del Mar García Navarro²⁹; Ana Cerezales Calviño³⁰; María Ángeles Garcinuño Jiménez³¹; Eva Estébanez³²; Miriam Ferreira Pasos³³; Beatriz de la Calle Riaguas³⁴; Teresa Omiste Sanvicente³⁵; Noemí Ramos Vicente³⁶; Marta Clavero Olmos³⁷; Juan Manuel Tiraboschi³⁸; Ana Lucas Dato³⁹; on behalf of the RELATIVITY PROJECT GROUP.

¹Hospital Vega Baja. FISABIO.UMH.CIBERINFEC, Orihuela, Spain; ²Fundación para la Investigación e Innovación Biomédica del Hospital Infanta Leonor, Madrid; ³Hospital Universitario La Paz, Madrid; ⁴Hospital Clínico Universitario de Valencia; ⁵Hospital Universitario Infanta Leonor, Madrid; ⁶Hospital de Burgos; ⁷Hospital Universitario de Guadalajara; ⁸Hospital Universitario 12 de Octubre, Madrid; ⁹Hospital Universitario La Princesa, Madrid; ¹⁰Hospital Universitario Fundación Jiménez Díaz, Madrid; ¹¹Hospital Clínico Universitario Lozano Blesa, Zaragoza; ¹²Hospital Universitario Álvaro Cunqueiro, Vigo; ¹³Hospital Clínico San Carlos, Madrid; ¹⁴Hospital de Denia; ¹⁵Hospital Universitario de Torrejón; ¹⁶Hospital Universitario San Agustín, Avilés; ¹⁷Hospital Universitario Puerta de Hierro, Majadahonda; ¹⁸Hospital Universitario de Fuenlabrada; ¹⁹Hospital Reina Sofía, Murcia; ²⁰Hospital Universitario Ramón y Cajal, Madrid; ²¹Hospital Universitario de Toledo; ²²Hospital General Universitario Gregorio Marañón, Madrid; ²³Hospital Universitario Miguel Servet, Zaragoza; ²⁴Hospital Universitario de Cabueñas; ²⁵Hospital General Universitario de Elche; ²⁶Hospital Universitario de Alcorcón; ²⁷Hospital Universitario Marqués de Valdecilla - IDIVAL CIBERINFEC, ISCIII, Santander; ²⁸Hospital General Universitario Morales Meseguer, Murcia; ²⁹Hospital Universitario de Vinalopo, Elche; ³⁰Hospital Universitario Doctor José Molina Orosa, Las Palmas;³¹Complejo Asistencial de Ávila, Ávila;³²Complejo Asistencial de Segovia;³³Hospital Central de la Defensa Gómez Ulla, Madrid; ³⁴Hospital General Nuestra Señora del Prado, Talavera de la Reina; ³⁵Hospital Universitario San Jorge, Huesca; ³⁶Hospital Obispo Polanco, Teruel; ³⁷Hospital Universitario Infanta Elena, Valdemoro; ³⁸Hospital Universitario de Bellvitge, Hospitalet de Llobregat; ³⁹Hospital Vega Baja.

BACKGROUND

Cabotegravir and rilpivirine (CAB+RPV) is the first long-acting injectable (LAI) treatment approved in Europe. However, limited data is available on its effectiveness in migrants, a highly mobile and vulnerable group, who often lack complete information on their baseline HIV-1 genotype, subtype, or previous antiretroviral therapy (ART) history.

RESULTS

Of the 1,350 HIV-positive patients who switched to LAI CAB+RPV, 396 (29.3%) were migrants, mostly from Latin America (figure 1). Migrants' countries of origin are shown in figure 2.

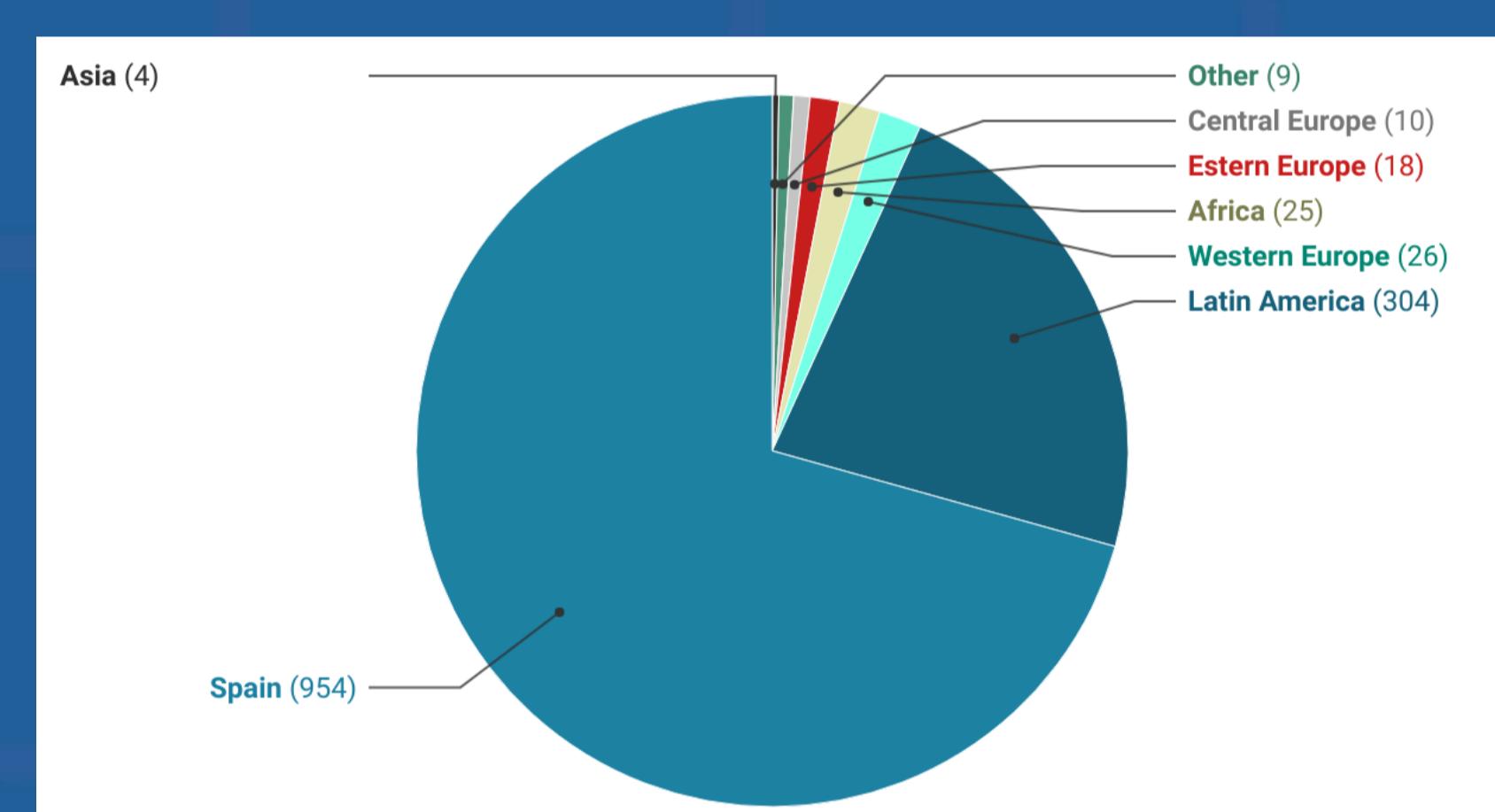


Figure 1. Area of origin of patients on CB+RPV in Relativity cohort

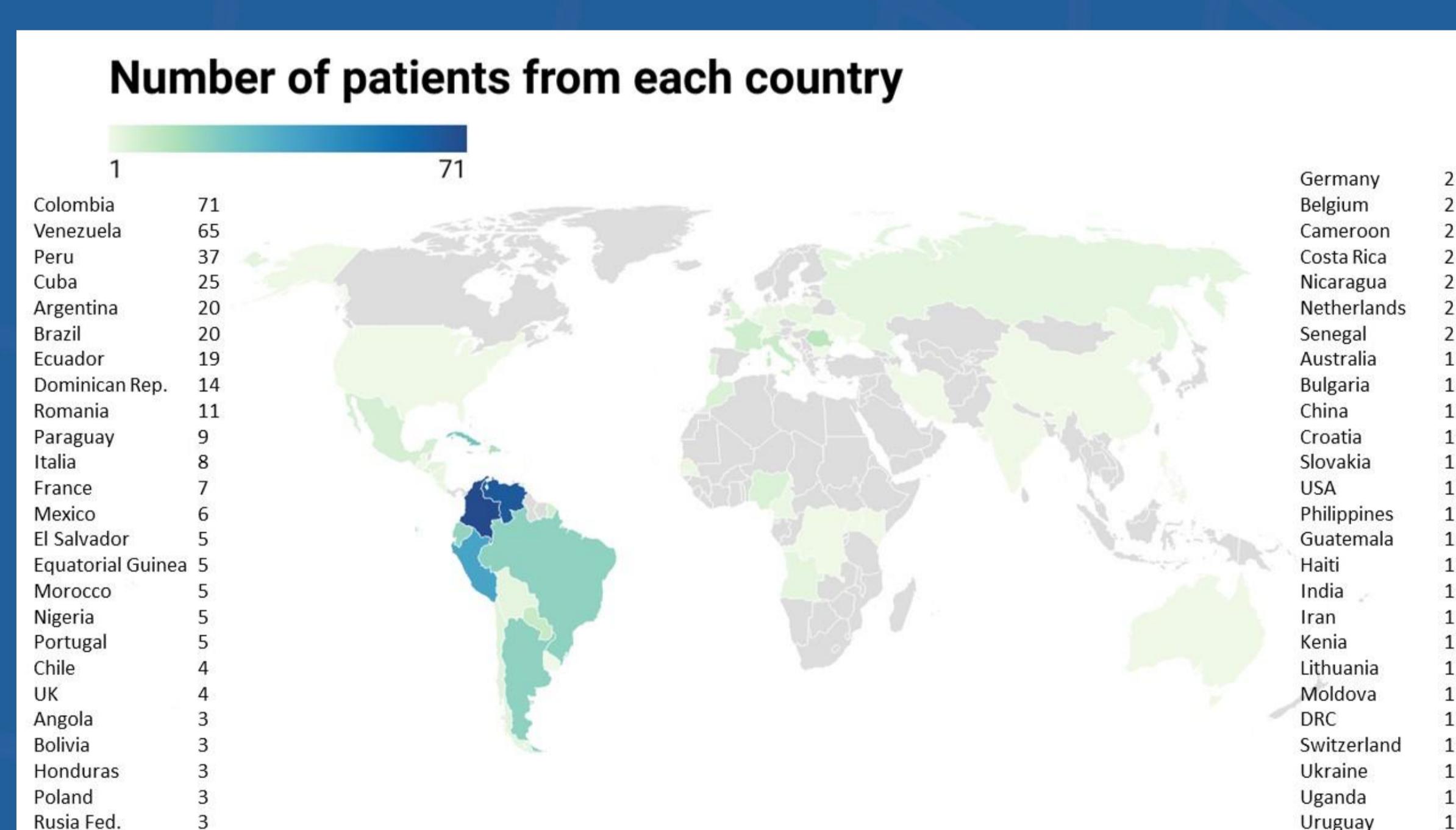


Figure 2. Country of origin of migrants on CB+RPV in Relativity cohort.
CAB: cabotegravir; RPV: rilpivirine

Migrants tended to be younger, a higher percentage were women and modes of HIV acquisition varied. Migrants had a shorter median duration of undetectable viral load before switching to LAI CAB+RPV and showed higher rates of certain non-B subtypes (Table 1).

After a median follow-up of 7.5 months, 7.1% of migrants discontinued LAI CAB+RPV, compared to 3.8% of Spanish-born patients (OR 2.10, 95%CI: 1.29-3.44) (figure 3). Side effects were a more frequent cause of discontinuation among migrants (OR: 2.65, 95%CI: 1.14-6.19), with local side effects being the most common. There were 6 cases of virological failure (3 in migrants and 3 in Spaniards, OR: 2.42, 95%CI: 0.49-12.04), and integrase mutations were detected in 2 migrants and 1 Spanish-born patient.

CONCLUSIONS

Nearly one-third of the patients switching to LAI CAB+RPV in this large Spanish cohort were migrants, primarily from Latin America. Migrant HIV-positive patients had double the risk of discontinuing LAI CAB+RPV compared to Spanish-born patients, with a higher likelihood of discontinuation due to side effects.

MATERIAL AND METHODS

A multicenter, non-controlled retrospective study was conducted, involving HIV-1 positive, virally suppressed patients who switched to CAB+RPV LAI from 37 hospitals in Spain. The baseline characteristics and outcomes of migrant patients were compared with those of Spanish-born patients. Quantitative variables were analyzed using the U-Mann-Whitney test, while categorical variables were compared using Chi-Square and Fisher's Exact tests.

	Migrants (n=396)	Spanish-born (n=954)	OR (95%CI) p-value
Age (years); median [IQR]	41.0 [33.0, 49.0]	47.0 [40.0, 57.0]	- <0.001
Sex: women	17.6%	13.6% 1.37 (0.98- 1.90)	0.062
Mode of HIV acquisition	GBMSM 71.0%	62.1% 1.49 (1.13 - 1.97)	0.003
Heterosexual	21.4%	17.9% 1.25 (0.91 - 1.70)	0.154
PID	1.4%	9.6% 0.13 (0.04 - 0.32)	<0.001
Other/unknown	6.2%	10.4% 0.63 (0.40 - 1.01)	0.052
Months from diagnosis to first ART; median [IQR]	2.0 [0.0, 6.0]	3.0 [1.0, 20.0]	- <0.001
Years on ART when starting CAB+RPV	7.0 [4.0, 11.0]	10.0 [6.0, 16.0]	- <0.001
Months of undetectability prior to CAB+RPV	60.0 [22.0, 108.0]	96.0 [48.2, 140.0]	- <0.001
Prior genotype test	Non-available 52.4%	44.9% 1.35 (1.05 - 1.74)	0.017
Wild type	64.6%	67.7% 0.87 (0.60 - 1.28)	0.514
INSTI mutations	1.7%	0.4% 4.30 (0.49 - 51.93)	0.114
NNRTI mutations	9.1%	6.2% 1.51 (0.75 - 2.94)	0.227
NRTI mutations	8.0%	9.9% 0.80 (0.39 - 1.51)	0.548
HIV-1 Subtype	B 47.4%	45.5% 1.08 (0.75 - 1.55)	0.660
A	2.9%	3.2% 0.88 (0.25 - 2.58)	1.000
F/CRF	6.3%	2.0% 3.26 (1.23 - 8.73)	0.010
Prior virological failure	3.0%	5.5% 0.54 (0.25 - 1.06)	0.079
Prior virological failure to NNRTI	0.6%	1.3% 0.45 (0.10 - 2.06)	0.306
BMI (kg/m2); median [IQR]	25.1 [22.2, 27.7]	24.5 [22.1, 27.2]	- 0.298

Table 1. Comparative analysis of basal characteristics between migrants and Spanish-born patients switching to long-acting injectable CAB+RPV in the Relativity cohort.

ART: antiretroviral treatment; BMI: body mass index; CAB: cabotegravir; GBMSM: gays, bisexuals and other men who have sex with men; INSTI: integrase strand transfer inhibitor; IQR: interquartile range; NNRTI: non-nucleoside reverse transcriptase inhibitor; NRTI: nucleoside reverse transcriptase inhibitor; OR: odds ratio; PID: people who inject drugs; RPV: rilpivirine; **bold**: statistically significant

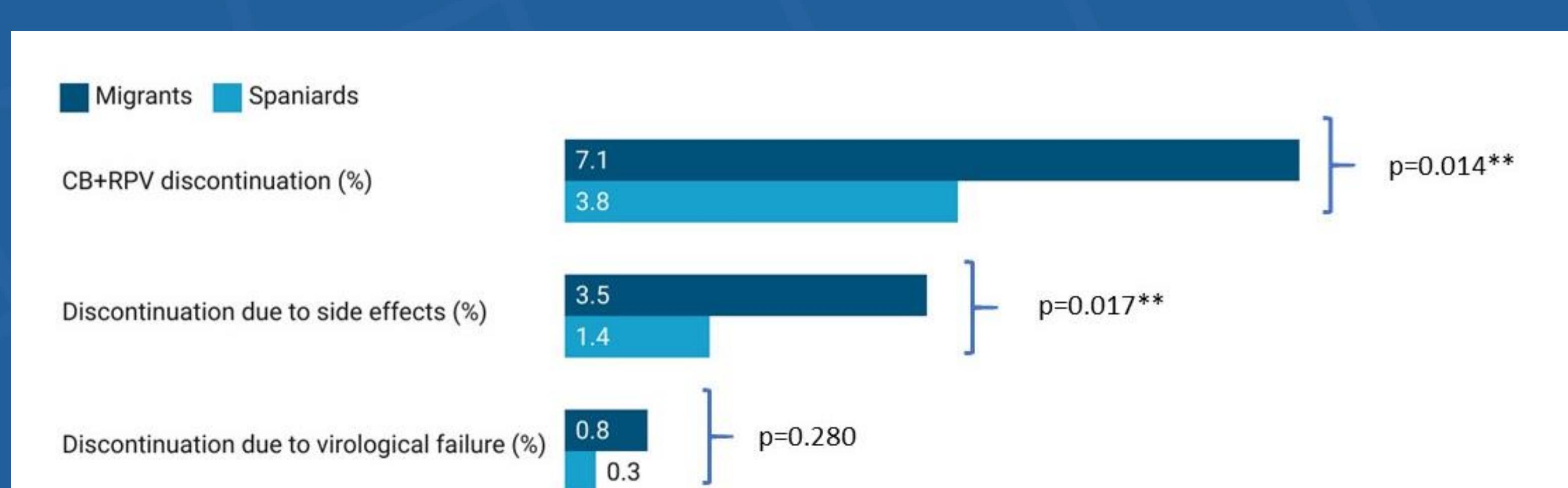


Figure 3. Main outcomes in migrants and Spanish-born patients switching to long-acting injectable CAB+RPV in the Relativity cohort.
CAB: cabotegravir; RPV: rilpivirine *Statistically significant

