Terapia Antirretroviral Long Acting en vida real en España

Jesús Troya

Hospital Universitario Infanta Leonor

Conflicto de interés

- He realizado ponencias para Janssen, Gilead y MSD. He colaborado en comité asesor para Janssen, ViiV y Gilead.

Cohorte RELATIVITY: 1.418 personas viviendo con VIH de 37 hospitales Españoles

RELATIVITY

Galicia (63)
1. Hospital Universitario Álvaro Cunqueiro (63)

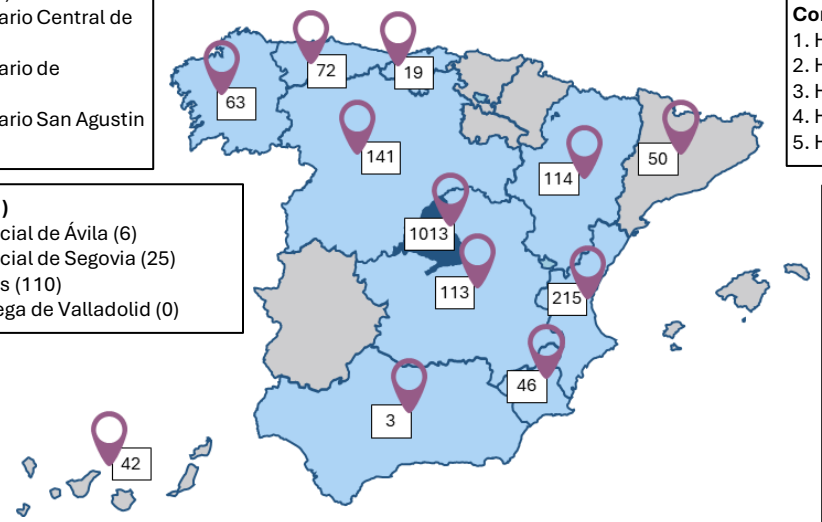
Cantabria (19)
1. Hospital Universitario Marqués de Valdecilla (19)

Aragón (114)
1. Hospital Clinico Universitario Lozano Blesa (82)
2. Hospital Obispo Polanco (4)
3. Hospital Universitario Miguel Servet (22)
4. Hospital Universitario San Jorge (6)

Cataluña (50)
1. Hospital del Mar (0)
2. Hospital Universitario de Bellvitge (50)
3. Parc Tauli Hospital Universitari (0)

Asturias (72)
1. Hospital de Jove (0)
2. Hospital Universitario Central de Asturias (0)
3. Hospital Universitario de Cabueñes (28)
4. Hospital Universitario San Agustin (44)

Comunidad Valenciana (215)
1. Hospital Clinico Universitario de Valencia (129)
2. Hospital Comarcal e la Vega Baja (18)
3. Hospital de Denia Marina Salud (25)
4. Hospital General Universitario de Elche (15)
5. Hospital Universitario de Vinalopo (8)



Castilla y León (141)
1. Complejo Asistencial de Ávila (6)
2. Complejo Asistencial de Segovia (25)
3. Hospital de Burgos (110)
4. Hospital Rio Hortega de Valladolid (0)

Comunidad de Madrid (1013)
1. Hospital Central de la Defensa Gómez Ulla (10)
2. Hospital Clinico San Carlos (50)
3. Hospital General Universitario Gregorio Marañón (19)
4. Hospital Universitario 12 de Octubre (124)
5. Hospital Universitario de Alcorcón (20)
6. Hospital Universitario de Fuenlabrada (40)
7. Hospital Universitario de Torrejón (33)
8. Hospital Universitario Fundación Jiménez Diaz (55)
9. Hospital Universitario Infanta Elena (3)
10. Hospital Universitario Infanta Leonor (192)
11. Hospital Universitario La Paz (292)
12. Hospital Universitario La Princesa (85)
13. Hospital Universitario Principe de Asturias (0)
14. Hospital Universitario Puerta de Hierro (40)
15. Hospital Universitario Ramón y Cajal (50)
16. Hospital Universitario Severo Ochoa (0)

Castilla La Mancha (133)
1. Hospital General Nuestra Señora del Prado (5)
2. Hospital Universitario de Guandalajara (101)
3. Hospital Universitario de Toledo (27)

Andalucía (3)
1. Hospital Universitario de Puerto Real (3)

Región de Murcia (46)
1. Hospital General Universitario Morales Meseguer (19)
2. Hospital General Universitario Reina Sofia (27)

Islas Canarias (42)
1. Hospital Universitario de Canarias (16)
2. Hospital Universitario Doctor José Molina Orosa (26)

- Estudio Español multicéntrico, no-controlado, ambispectivo [1]
- Cohorte incluye personas suprimidas con VIH que cambiaron a LA CAB + RPV [1]
- SUBESTUDIOS:
  - Edad >60 años (IDWeek 2024)[2]
  - Mujeres (HIV Glasgow 2024)[3]
  - Transgénero (HIV Glasgow 2024)[4]
  - Migrantes (HIV Glasgow 2024)[5]
  - IMC>30 (HIV Glasgow 2024)[6]
  - Genotipo (HIV Glasgow 2024)[7]
  - Cambio desde DTG/RPV (HIV Glasgow 2024)[8]

IMC, índice de masa corporal; **CAB,** cabotegravir; **DTG,** dolutegravir **LA,** long acting; **RPV,** rilpivirina

1. Buzón-Martín L, et al. HIV Glasgow 2024. Poster P056; **2.** Troya J, et al. IDWeek 2024. Poster 561
3. Puerto MJG, et al. HIV Glasgow 2024. Poster 065; **4.** de Santiago AD, et al. HIV Glasgow 2024. Poster P189
5. Buzón-Martín L, et al. HIV Glasgow 2024. Poster P064; **6.** Troya J, et al. HIV Glasgow 2024. Poster P081
7. Buzón-Martín L, et al. HIV Glasgow 2024. Poster P079; **8.** Buzón-Martín L, et al. HIV Glasgow 2024. Poster P104

Cohorte de vida real RELATIVITY

RELATIVITY

Tiempo medio de seguimento (IQR)

7.6 meses (5–11)

Edad media (IQR)

45 años (37–54)

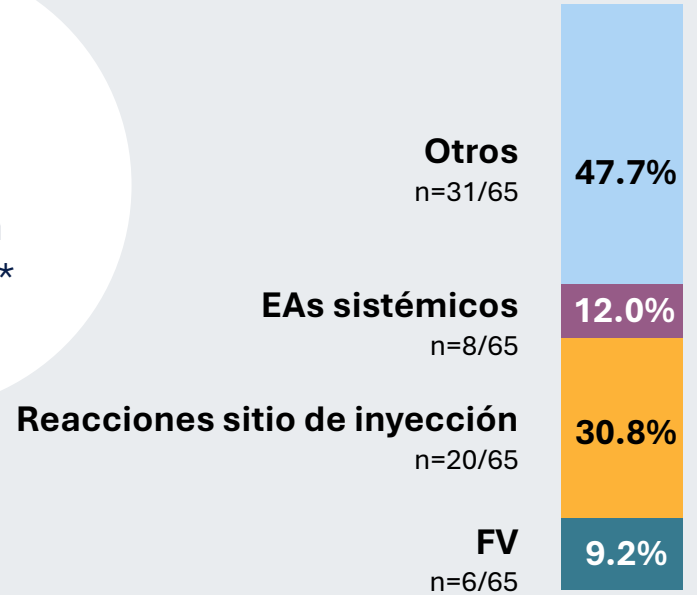
1,285 personas viviendo con VIH tratadas con LA CAB + RPV LA fueron incluidas en el análisis

95%
(n=NR)

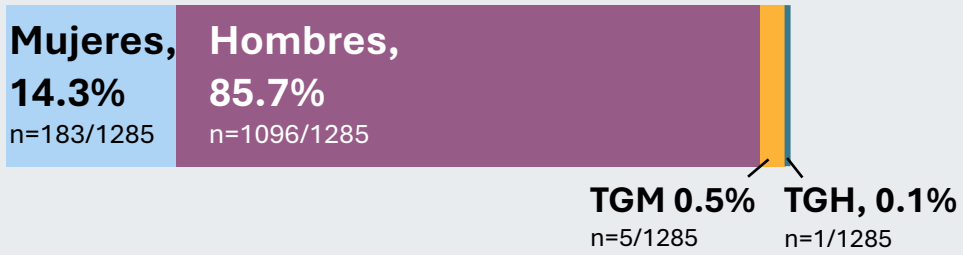
Supresión Virológica *

6 FVs (0.5%)
RAMs detectadas en 3 personas

Discontinuaciones ocurrieron en 65 personas (5.1%):



Sexo

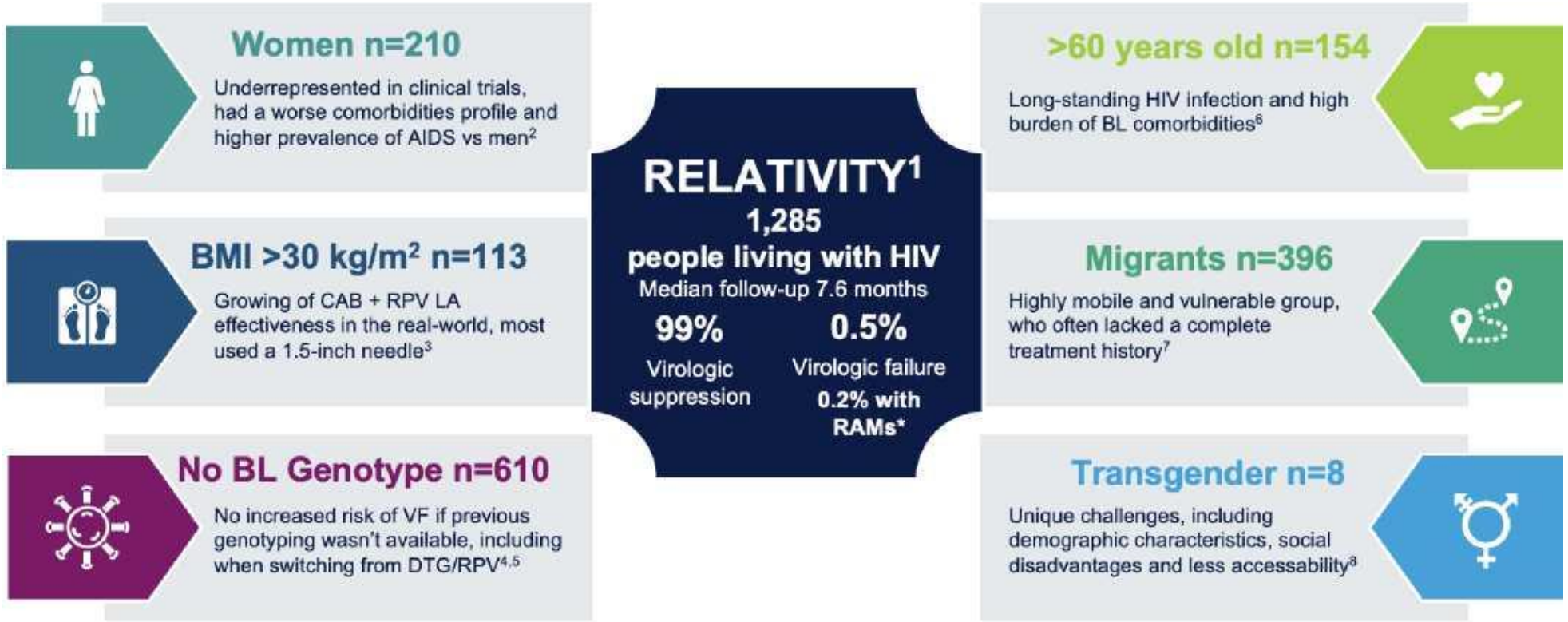


*Carga viral indetectable entre 95.5% y 100% a lo largo del period de estudio.
EA, evento adverso; **IQR,** rango intercuarltílico; **RAM,** mutaciones de resistencia asociadas; **MTG**, mujer transgénero **HTG,** hombre transgénero; **FV,** fallo virológico

Buzón-Martín L, et al. HIV Glasgow 2024. Poster P05

Subestudios de Cohorte RELATIVITY

RELATIVITY



1. Buzón Martín L, et al. HIV Glasgow 2024. Poster P056; 2. Galindo Puerto MJ, et al. HIV Glasgow 2024. Poster P065 3. Troya J, et al. HIV Glasgow 2024. Poster P081; 4. Buzón Martín L, et al. HIV Glasgow 2024. Poster P079 5. Galindo Puerto MJ, et al. HIV Glasgow 2024. Poster P104; 6. Troya J, et al. IDWeek 2024. Poster P-561 7. Llenas Garcia J, et al. HIV Glasgow 2024. Poster P064; 8. Díaz de Santiago A, et al. HIV Glasgow 2024. Poster P189

VARIABLES ASOCIADAS A FRACASO

Subestudio IMC >30. Cohorte RELATIVITY

RELATIVITY

HIV DRUG THERAPY GLASGOW 2024 P081

LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN HIV INDIVIDUALS WITH A BMI OVER 30: A REAL-WORLD STUDY (RELATIVITY COHORT)

Jesús Troya, Luis Morano, Jose Ignacio Bernardino, Luis Buzón, Roberto Pedrero-Tomé, María José Galindo, Miguel Torralba, Noemí Cabello, María García, Mar Masià, Miguel Alberto de Zárraga, Alfonso Cabello, María Aguilera, Álvaro Cecilio, Alberto Díaz de Santiago[1], María Ángeles Garcinuño, Enrique Bernal, Mireia Santacreu, Ruth Calderón, María Jesús Vivancos, Teresa Omiste, Eva Ferreira, Juan Emilio Losa, Josefa Soler, María Antonia Sepúlveda, María del Mar García, on behalf of the RELATIVITY PROJECT GROUP

BACKGROUND

Switching to long-acting cabotegravir and rilpivirine (CAB+RPV) has emerged as a standard approach for people living with HIV (PLWH), offering high efficacy, safety, and convenience. Nevertheless, there is a scarcity of data regarding people with a body mass index (BMI) over 30, a factor potentially related to virological failure in studies.

MATERIAL AND METHODS

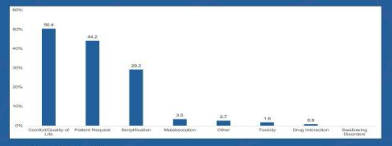
We conducted a multicenter, non-controlled, retrospective study on HIV virologically suppressed individuals who switched to long-acting CAB+RPV (RELATIVITY Cohort) in 2023 We evaluated demographic and clinical factors in individuals with a BMI > 30.

RESULTS

The study included 113 individuals from 25 hospitals in Spain, representing 8.3% of the Relativity cohort, which comprised 1366 individuals. The median age was 48 years (41 to 54), with 78.8% being men. The median duration of previous oral antiretroviral therapy was 10.7 years (IQR: 6.0 - 17.0), and the median duration of viral suppression was 8.0 years (IQR: 4.6 - 12.0).

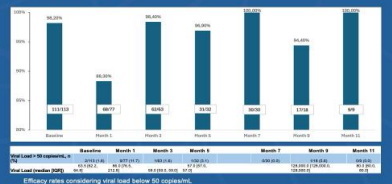
The median BMI at the time of switching to long-acting CAB+RPV was 32.3 [IQR: 30.9 - 34.1]. A 38mm needle was used in 56.7% of cases. Intramuscular injections were applied to the dorsogluteal location in 79.3% of individuals.

The main reasons for switching were improvement in quality of life (50.4%), patient request (44.2%)



At week 24, one patient had an isolated detectable viral load of 57 copies/mL but continued treatment. At week 39, there were two virological failures, both with previous resistance mutations (one to INSTIs using a short needle and the other to NNRTIs).

Three discontinuations due to injection site side effects occurred at weeks 21, 29, and 30.



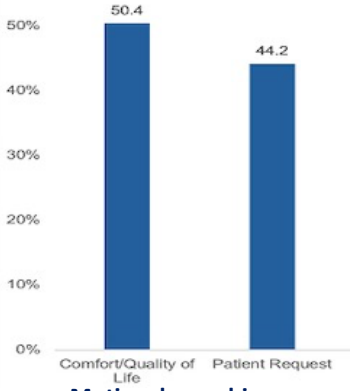
There were no significant changes in the analytical values, including the metabolic, renal, or hepatic profile, during the first 11 months

	Baseline (N: 88 - 110)	Month 1 (N: 9 - 15)	Month 3 (N: 27 - 32)	Month 5 (N: 19 - 21)	Month 7 (N: 17 - 24)	Month 9 (N: 11 - 12)	Month 11 (N: 3 - 5)
CD4 (cells/mm3)	789.5 [692.5, 993.5]	765.0 [622.0, 907.0]	809.6 [494.0, 897.0]	767.0 [641.0, 870.5]	764.0 [695.0, 987.0]	669.0 [505.0, 940.0]	778.0 [678.0, 1045.2]
CD4%	34.0 [28.2, 39.5]	34.7 [30.5, 35.0]	33.0 [26.4, 39.0]	38.0 [30.7, 42.5]	31.7 [24.5, 38.5]	33.4 [31.5, 35.5]	35.1 [27.0, 42.9]
CD8 (cells/mm3)	855.5 [641.5, 1094.2]	819.0 [602.0, 991.0]	753.0 [605.5, 952.5]	787.0 [530.0, 998.5]	892.5 [570.0, 1291.8]	606.0 [538.0, 954.0]	1119.0 [809.0, 1354.2]
CD4/CD8	1.0 [0.7, 1.3]	1.0 [0.7, 1.3]	1.0 [0.6, 1.2]	1.3 [0.8, 1.4]	0.9 [0.6, 1.2]	0.9 [0.8, 1.2]	1.0 [0.7, 1.3]
Glucose (mg/dL)	96.0 [89.0, 104.0]	104.0 [84.0, 113.5]	94.5 [85.0, 103.2]	101.0 [91.0, 107.0]	96.0 [90.0, 101.2]	102.0 [92.0, 108.8]	91.0 [87.0, 97.0]
HbA1c (%)	5.8 [5.3, 6.4]	7.2 [6.0, 8.9]	7.0 [5.9, 9.3]	5.9 [5.8, 9.0]	5.4 [5.3, 5.6]	6.1 [6.1, 6.1]	6.0 [5.8, 21.0]
Cholesterol (mg/dL)	195.0 [160.0, 208.0]	165.0 [147.0, 204.0]	183.0 [151.0, 214.0]	177.5 [155.5, 196.0]	190.0 [170.5, 207.5]	176.0 [156.8, 203.2]	183.0 [161.0, 191.0]
LDL Cholesterol (mg/dL)	116.5 [97.2, 136.0]	113.0 [97.0, 132.0]	112.0 [85.0, 143.0]	109.0 [86.5, 128.0]	119.0 [95.5, 134.0]	118.5 [97.8, 141.0]	107.0 [107.0, 110.0]
HDL Cholesterol (mg/dL)	42.0 [36.0, 49.0]	43.0 [42.0, 46.0]	47.0 [38.0, 55.0]	40.0 [35.5, 46.0]	44.0 [38.8, 51.8]	38.0 [35.5, 43.2]	44.0 [43.0, 52.0]
Triglycerides (mg/dL)	131.0 [92.0, 181.0]	115.0 [76.2, 122.8]	117.0 [85.0, 162.0]	124.5 [80.8, 178.5]	112.5 [76.5, 165.0]	134.0 [102.5, 156.0]	145.0 [97.0, 167.0]
AST (U/L)	22.5 [18.0, 27.8]	19.0 [13.2, 23.0]	23.0 [19.0, 32.0]	20.0 [18.0, 30.5]	24.0 [19.5, 27.0]	25.5 [18.8, 28.8]	20.0 [15.5, 29.0]
ALT (U/L)	26.5 [20.8, 37.0]	18.0 [16.2, 26.0]	31.0 [22.2, 41.2]	26.0 [17.5, 42.0]	31.0 [23.2, 38.0]	33.5 [18.8, 46.0]	19.0 [16.0, 32.0]
GGT (U/L)	30.0 [19.5, 44.0]	28.0 [19.5, 36.5]	33.0 [21.5, 57.5]	25.0 [18.0, 30.0]	28.5 [18.8, 45.2]	38.5 [32.0, 79.0]	29.0 [27.0, 32.0]
Creatinine (mg/dL)	0.9 [0.8, 1.1]	0.9 [0.8, 0.9]	0.9 [0.8, 0.9]	0.8 [0.8, 1.0]	0.9 [0.8, 1.0]	0.9 [0.8, 1.0]	0.9 [0.7, 1.0]
Estimated Glomerular Filtration Rate (ml/min/1.73m2)	89.0 [78.0, 91.7]	91.0 [88.4, 98.4]	91.0 [82.0, 97.0]	86.0 [78.2, 91.0]	89.0 [84.0, 91.0]	91.0 [89.0, 99.2]	91.0 [82.0, 99.2]

Analytical values (median and IQR) during the first 11 months after switching to long-acting CAB+RPV. N varies for each variable

CONCLUSIONS

In a real-life setting, switching to long-acting CAB+RPV seems to be a viable option for individuals with a BMI over 30, lining up with other cohorts. Further investigation is needed



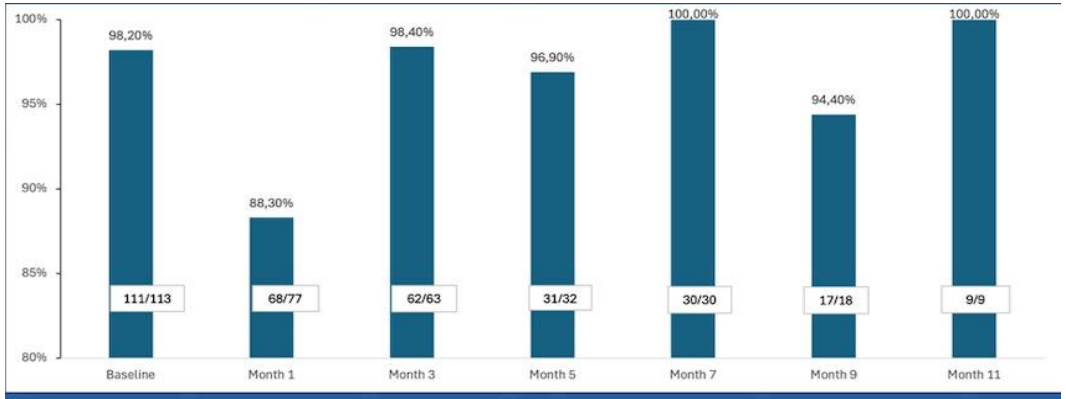
Motivo de cambio

113

La mediana del IMC en el momento del cambio a CAB+RPV de acción prolongada fue de 32.3 [IQR: 30.9 - 34.1]

Aguja de 38 mm en el 56.7% de los casos. Región dorsoglútea en el 79.3% de los individuos

HIV DRUG THERAPY GLASGOW 2024



	Baseline	Month 1	Month 3	Month 5	Month 7	Month 9	Month 11
Viral Load > 50 copies/mL, n (%)	2/113 (1.8)	9/77 (11.7)	1/63 (1.6)	1/32 (3.1)	0/30 (0.0)	1/18 (5.6)	0/9 (0.0)
Viral Load (median [IQR])	63.5 [62.2, 64.8]	86.0 [76.5, 212.8]	59.0 [59.0, 59.0]	57.0 [57.0, 57.0]		128,000.0 [128,000.0, 128,000.0]	80.0 [80.0, 80.0]

Eficacia en 11 primeros meses

Fracasos: MR previas, INI(Q148K, Q148R, E157Q) y ITINAN (G140S, L74M/I/F, T97A

Troya et al.Glasgow 2024

IMC >30 con LA CAB+RPV

Clinical Infectious Diseases

JOURNAL ARTICLE CORRECTED PROOF

Real World Virologic Outcomes in Patients With Elevated Body Mass Index Receiving Long Acting Cabotegravir/Rilpivirine

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	BMI <30 kg/m^2 (n=226)	BMI ≥ 30 kg/m^2 (n=148)	Overall (N=374)	IRR	95% CI	p-value
VL >50 copies/mL at Last Observed Endpoint	21 (9 %)	18 (12 %)	39 (10 %)	1.31	0.69, 2.46	0.4
Confirmed Virologic Failure	1 (0.4%)	2 (1.4%)	3 (0.8%)			
Days on LA-CAB/RPV, Median [IQR]	255.5 [147, 363.5]	254 [152.25, 340]	255 [147.25, 361.5]			

> Clin Infect Dis. 2025 Feb 5:ciaf024. doi: 10.1093/cid/ciaf024. Online ahead of print.

Long-Acting CAB Plus RPV: It's Not About Weight, It's About the Weight of the Evidence

Jesús Troya [1], María Luisa Montes [2 3], Juan Emilio Losa [4], Luis Buzón-Martín [5]

Clin Infect Dis. 2024 Nov 27:ciae579. doi: 10.1093/cid/ciae579

Subestudio Genotipo. Cohorte RELATIVITY

RELATIVITY

HIV DRUG THERAPY GLASGOW 2024

P059

SWITCHING LA CBG/RPV IN VIROLOGICALLY SUPPRESSED PLHIV. DOES KNOWING PREVIOUS GENOTYPING REALLY MATTER? A SUBESTUDY FROM THE RELATIVITY COHORT

Luis Buzón Martín, María Luisa Montes, María José Galindo Puerto, Miguel Torralba, Victoria Mancheño De Real, María Aguilera García, Alfonso Cabello Úbeda, Isabel San Joaquín Conde, Luis Morano, Noemí Cabello Clotet, Patricia Martín Rico, Carmen Montero Hernández, Miguel de Zárraga Fernández, Sara De la Fuente, Ruth Calderón Hernaiz, Enrique Bernal, María Jesús Vivancos Gallego,María Antonia Sepúlveda, Roberto Pedrero-Tomé, Cristina Díez Romero, Álvaro Cecilio, Jara Llenas García, Víctor Arenas García, Mar Masiá Canuto, Juan Emilio Losa García, Carlos Armiñanzas Castillo, Antonio Jesús Sánchez Guirao, María del Mar García Navarro, Ana Cerezales Calviño, María Ángeles Garcinuño Jiménez, Eva Ferreira Pasos, Miriam Estébanez, Beatriz De la Calle Riaguas, Miguel Egido Murciano, Noemí Ramos Vicente, Marta Clavero Olmos, Juan Manuel Tiraboschi, Jesús Troya, **on behalf of the RELATIVITY Project**

BACKGROUND

Resistance associated mutations (RAMs) to RPV and/or INSTI, along with BMI>30 and HIV subtype A1/A6, increase the risk of CBG/RPV-associated virological failure. The aim of the current substudy is to compare efficacy outcomes in real life in virologically suppressed PLHIV who switched to CBG/RPV according to whether previous genotyping was available or not at the time of switching.

MATERIAL AND METHODS

The relativity cohort is a nationwide Spanish cohort of PLHIV older than 18 years old treated with CBG/RPV. Patients coming from CBG/RPV clinical trials are not included. 1285 cases from 37 institutions are described. Cuantitative variables are compared usingthe U-Mann Whitney test and qualitative variables using Chi-Square and/or Fisher´s exact test.

RESULTS

The group in which previous genotyping results were available comprised 675/1285 cases (52.5%) (see table 1). Within this group, spanish nationality was more common (74% vs 67.7%; p-value=0.012), older (46.0 years old [37.0, 56.0] vs 44.0 [37.0, 52.0]; p= 0.012) and had more psychiatric disorders (11.1% vs 7.0%; p=0.015); Besides, blips (33.0% vs 15.0%; p=0.005) and documented virological failures with any oral ART before switching (5.9% vs 3.2%; p<0.001) were more frequent in it. Time on oral ART until switch to LA CBG/RPV was significantly shorter in this group (9.0 [5.0, 12.0] vs 10.0 [6.0, 18.0] years; p-value <0.001), as was the length of the period with undetectable viral load in plasma before switching (73.0 [37.2, 117.0] vs 96.0 [45.0, 156.0] months; p-value<0.001).Switching from DTG/RPV (27.5%vs 19.6%; p<0.001) or DRV-based regimens (8.2% vs 3.6%, p<0.001) (figure 2). was more frequent when genotyping was unavailable. There were no statistically significant differences in time of follow up, CD4 T cell count at the time of switch, abandon rate, or the development of virological failure (tables 1 and 2)

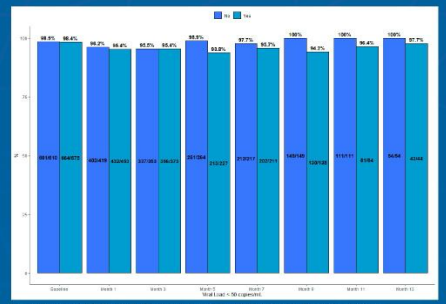
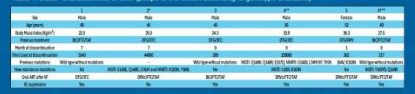


Figure 1: Percentage of PLHIV with VL<50 copies/mL in both subgroups throughout the different follow up periods

Figure 2: Oral ART previous to switch in both groups

Table 1. Basal characteristics of both groups of the cohort according to genotype availability



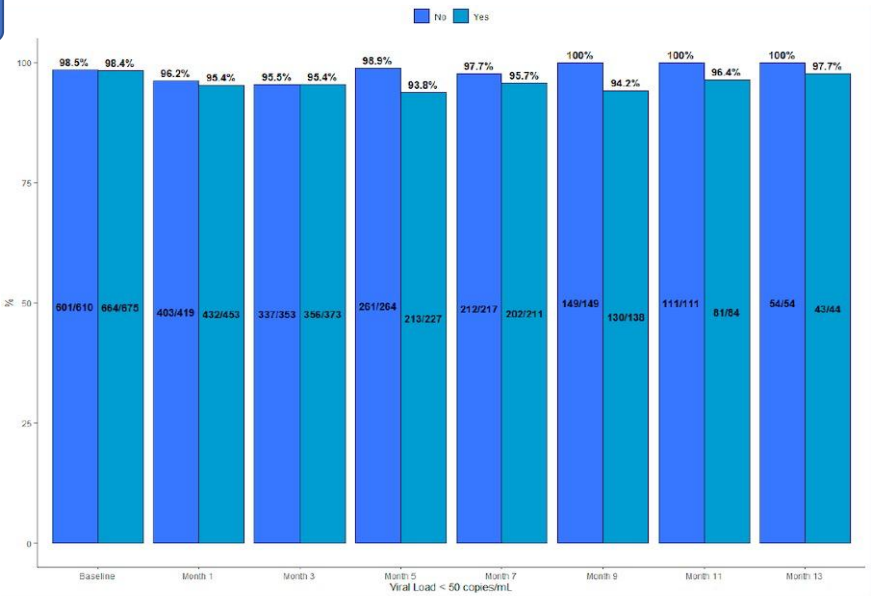
*Screening failure. Previous VF with probable RAMs against INSTI unnoticed. **Patient with baseline mutations not known at the moment of switch
*** Patient undetectable at the time of switch to oral ART. Two previous viral loads >200, last 217. In spite of it, resistances to INSTI were detected

CONCLUSIONS

Our results suggest that unavailability of previous genotyping doesn´t seem to increase the risk of virological failure in virologicallysuppresed PLHIV who switch to LA CBG/RPV. These seems to line up with the results of the CARES study. Nevertheless, alonger follow up is required to reach solid conclusions.

RELATIVITY

610



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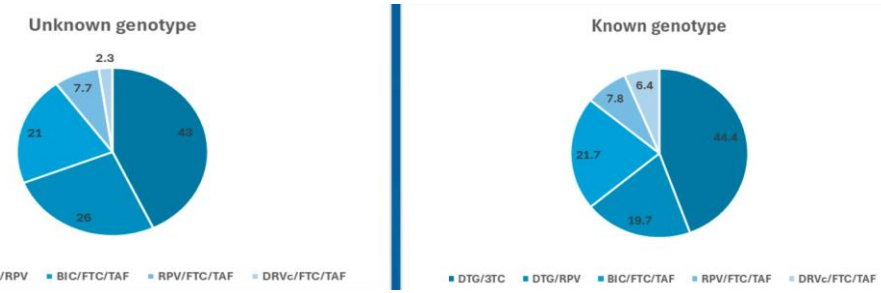
Eficacia en 11 primeros meses



NO incremento del riesgo de fracaso virológico

Buzón et al.Glasgow 2024

POBLACIONES ESPECIALES

Subestudio > 60 años. Cohorte RELATIVITY

RELATIVITY

1825788

LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN HIV INDIVIDUALS OVER 60 YEARS: A REAL-WORLD STUDY (RELATIVITY COHORT)

Jesús Troya, Enrique Bernal, Luis Morano, María Luisa Montes, María Josefa Galindo, María José Crusells, Miguel Torralba, Maite López, Juan Emilio Losa, Miguel de Zárraga, Ignacio Santos, Noemí Cabello, Patricia Martín, Mar Masiá, Alfonso Cabello, María Antonia Sepúlveda, Claudia González, Alberto Díaz, María Jesús Vivancos, Jara Llenas, María del Carmen Montero, Beatriz de la Calle, Ruth Calderón, María del Mar García, Álvaro Cecilio, Roberto Pedrero Tomé and Luis Buzón.

jestrogar@hotmail.com

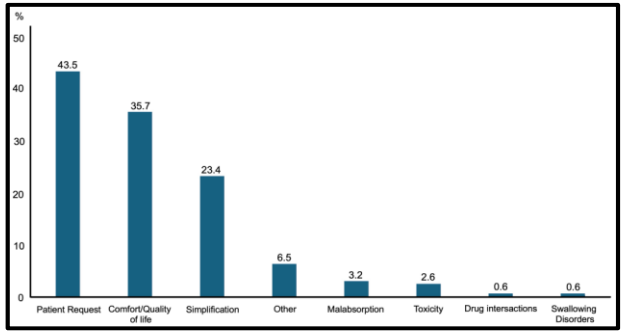
BACKGROUND: Despite switching to long-acting cabotegravir and rilpivirine (CAB+RPV) offers high efficacy, safety, and convenience rates, there is a scarcity of data regarding older PLWH, an important and growing population with physiological differences and arising co-morbidities.

METHODS: We conducted a multicenter, non-controlled, retrospective study (Relativity cohort) on HIV virologically suppressed individuals who switched to long-acting intramuscular CAB+RPV every two months. We evaluated the demographic and clinical factors associated with this switch in individuals over 60 years of age.

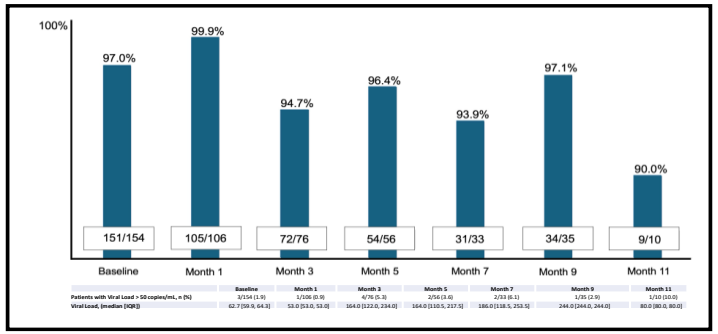
RESULTS: The study included 154 individuals from 27 hospitals in Spain, with a median age of 63 (range 61 to 68) years, and 77.9% being men. Comorbidities were present in 70.1% of individuals and the most prevalent comorbidities were dyslipidemia (45.5%), high blood pressure (32.5%), and osteoporosis (19.5%).
The median time since HIV diagnosis was 22 years (range 13 to 31), the median duration of antiretroviral therapy was 18 years (range 11 to 24), and the median duration of viral suppression was 12 years (range 8 to 17). Previous virological failures had been registered in 9 (5.8%) patients, including resistance mutations in 100% (NRTIs or PIs). The main reasons for switching were patient request (43.5%), improvement in quality of life (35.7%), and simplification (23.4%). The efficacy rates at months 5 and 9 were 96.4% and 97.1% respectively, with no virological failures, despite detected viral blips.

Demographic Data	(n=154)
Age (years), (median [IQR])	63.4 (61.0, 68.0)
Male, n (%)	120/154 (77.9)
Spaniards, n (%)	136/152 (89.5)
Comorbidities, n (%)	
High Blood Preassure	50/154 (32.5)
Diabetes Mellitus	21/154 (13.6)
Dyslipidemia	70/154 (45.5)
Ischemic Heart Disease	6/154 (3.9)
Cerebrovascular Disease	5/154 (3.2)
Peripheral Vascular Disease	2/154 (1.3)
Renal Insufficiency	5/154 (3.2)
Osteopenia/Osteoporosis	30/154 (19.5)
Chronic Lung Disease	12/154 (7.8)
Psychiatric Disorder	12/154 (7.8)
Active Oncological Disease	4/154 (2.6)
Alcoholic Liver Disease	1/154 (0.6)
Chronic Liver Disease	13/154 (8.4)
Non-Alcoholic Fatty Liver Disease (NAFLD)	10/154 (6.5)
Active Hepatitis C	0/154 (0.0)
Active Hepatitis B	0/154 (0.0)
Transmission Route, n (%)	
Gays Bisexuals and other Men who have Sex with Men	60/154 (42.6)
Heterosexual	39/154 (27.7)
Injection Drug Users	28/154 (19.9)
Vertical	0/154 (0.0)
Others	2/154 (1.4)
Not available	12/154 (8.5)
HIV History	
NADIR CD4, (median [IQR])	240.0 [111.5, 374.0]
Viral Load at Diagnosis, (median [IQR])	50400.0 [19885.0, 190000.0]
Time from Diagnosis to Start of First ART (years), (median [IQR])	6.0 [1.0, 54.8]
AIDS, n (%)	34/139 (24.5)
Time on ART from Start of Treatment to Start of CBG/RPV (years), (median [IQR])	18.0 [11.0, 24.0]
Time to Undetectability Until Start of CAB+RPV (months), (median [IQR])	144.0 [96.0, 204.0]
Previous Virological Failure, n (%)	9/142 (6.3)
Reason for switching, n (%)	
Toxicity	4/154 (2.6)
Drug Interaction	1/154 (0.6)
Simplification	36/154 (23.4)
Comfort/Quality of Life	55/154 (35.7)
Malabsorption	5/154 (3.2)
Swallowing Disorders	1/154 (0.6)
Patient Request	67/154 (43.5)
Other	10/154 (6.5)
Previous Treatment, n (%)	
DTG/3TC	49 (31.8)
DTG/RPV	44 (28.6)
BIC/FTC/TAF	25 (16.2)
DRV/c/FTC/TAF	8 (5.2)
EFV/FTC/TDF	3 (1.9)
Treatment Discontinuation, n (%)	
Treatment Discontinuation, n (%)	8/154 (5.2)
Days of Treatment Until Discontinuation, (median [IQR])	90.0 [33.0, 155.0]
Systemic Adverse Effects, n (%)	2/8 (22.2)
Related to Injection Site Reaction, n (%)	2/8 (22.2)
Virological Failure, n (%)	0/8 (0.0)
Other, n (%)	4/8 (44.4)

Main characteristics of the study population of individuals over 60 years of age



Main reasons for switching to long-acting CAB+RPV every 2 months in individuals over 60 years of age



Efficacy rates considering viral load < 50 copies/ml during follow-up, with available data, including viral blips

	Baseline (N: 120 - 134)	Month 1 (N: 22 - 30)	Month 3 (N: 37 - 48)	Month 5 (N: 30 - 35)	Month 7 (N: 18 - 20)	Month 9 (N: 27 - 30)	Month 11 (N: 4 - 7)
CD4 (cells/mm3)	790.0 [539.8, 972.8]	779.0 [571.5, 883.2]	683.0 [544.2, 857.2]	763.0 [628.0, 905.0]	700.0 [654.0, 990.0]	657.0 [463.5, 816.0]	961.0 [842.0, 1179.0]
CD4 %	33.2 [26.6, 41.0]	35.5 [32.2, 40.8]	34.0 [28.0, 39.0]	31.9 [28.6, 39.2]	36.7 [30.9, 44.9]	35.8 [27.5, 40.5]	34.3 [29.6, 43.0]
CD8 (cells/mm3)	814.0 [512.5, 1140.5]	747.5 [457.8, 948.5]	740.5 [596.0, 1022.5]	802.5 [510.0, 1222.0]	728.0 [597.2, 1112.0]	643.0 [432.5, 923.5]	1128.0 [1065.0, 1238.0]
CD4/CD8	0.9 [0.6, 1.4]	1.0 [0.8, 1.3]	0.9 [0.7, 1.2]	0.9 [0.7, 1.2]	0.9 [0.7, 1.1]	1.1 [0.7, 1.5]	0.8 [0.6, 1.2]
Glucose (mg/dL)	98.0 [91.0, 110.0]	98.5 [86.8, 107.0]	102.0 [89.2, 113.2]	96.0 [90.5, 105.5]	92.5 [86.5, 102.2]	101.0 [90.5, 111.2]	95.0 [90.5, 110.5]
Cholesterol (mg/dL)	174.0 [153.0, 201.0]	179.0 [150.0, 198.0]	180.0 [153.8, 202.2]	168.0 [140.5, 187.0]	183.5 [159.2, 220.0]	190.0 [167.2, 217.0]	194.0 [177.5, 195.5]
LDL Cholesterol (mg/dL)	99.0 [83.0, 124.0]	107.0 [90.8, 129.5]	105.5 [83.8, 121.2]	93.0 [66.8, 108.7]	110.5 [81.8, 134.0]	110.5 [90.8, 119.5]	112.0 [99.5, 114.8]
HDL Cholesterol (mg/dL)	49.0 [42.0, 59.0]	44.0 [38.0, 53.0]	53.0 [44.0, 63.0]	49.0 [42.5, 62.0]	46.0 [38.5, 60.2]	44.5 [41.2, 66.0]	51.0 [47.0, 54.2]
Triglycerides (mg/dL)	111.0 [83.0, 150.0]	111.5 [88.0, 153.8]	102.0 [79.8, 155.5]	112.5 [78.5, 160.5]	135.0 [94.0, 212.2]	94.0 [75.0, 119.0]	107.0 [82.5, 129.5]
AST (U/L)	23.0 [18.0, 28.0]	23.0 [16.0, 25.0]	24.0 [18.8, 29.0]	23.5 [19.0, 32.5]	22.5 [19.8, 28.0]	22.0 [17.0, 27.0]	17.0 [16.0, 23.5]
ALT (U/L)	21.0 [17.0, 29.0]	21.5 [17.2, 30.5]	22.5 [18.0, 30.0]	23.0 [18.0, 33.0]	21.0 [17.0, 33.0]	23.0 [19.0, 27.2]	18.0 [15.5, 20.0]
GGT (U/L)	28.0 [20.0, 44.0]	29.5 [22.8, 53.2]	31.5 [22.8, 48.5]	26.0 [16.8, 34.5]	31.0 [21.8, 56.5]	36.0 [25.5, 44.0]	28.5 [22.2, 38.0]
Creatinine (mg/dL)	1.0 [0.9, 1.1]	0.9 [0.8, 1.0]	0.9 [0.8, 1.0]	0.9 [0.8, 1.1]	0.8 [0.8, 1.0]	0.9 [0.7, 1.0]	0.8 [0.8, 0.9]
Estimated Glomerular Filtration Rate (ml/min/1.73m²)	75.0 [63.0, 87.0]	71.5 [61.0, 83.0]	81.7 [67.0, 91.0]	74.0 [66.2, 87.2]	81.6 [70.2, 90.8]	82.0 [78.3, 89.5]	90.6 [75.5, 91.0]

Changes in analytical values during follow-up (median [IQR]). N varies for each variable

CONCLUSIONS: In a real-life setting, switching to CAB+RPV proves to be a viable option for individuals over 60 years old, with long-standing HIV infection and a high burden of baseline comorbidities, demonstrating sustained virological control over the initial 24 weeks of this treatment.

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Subestudio > 60 años. Cohorte RELATIVITY

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Age (years), (median [IQR])	63.4 [61.0, 68.0]
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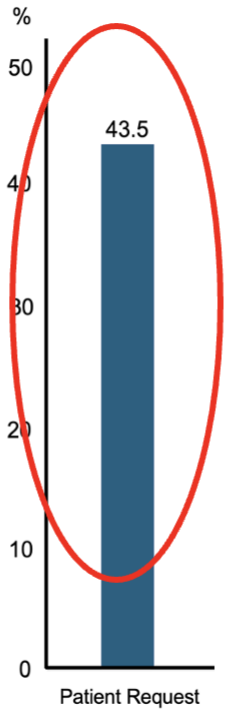

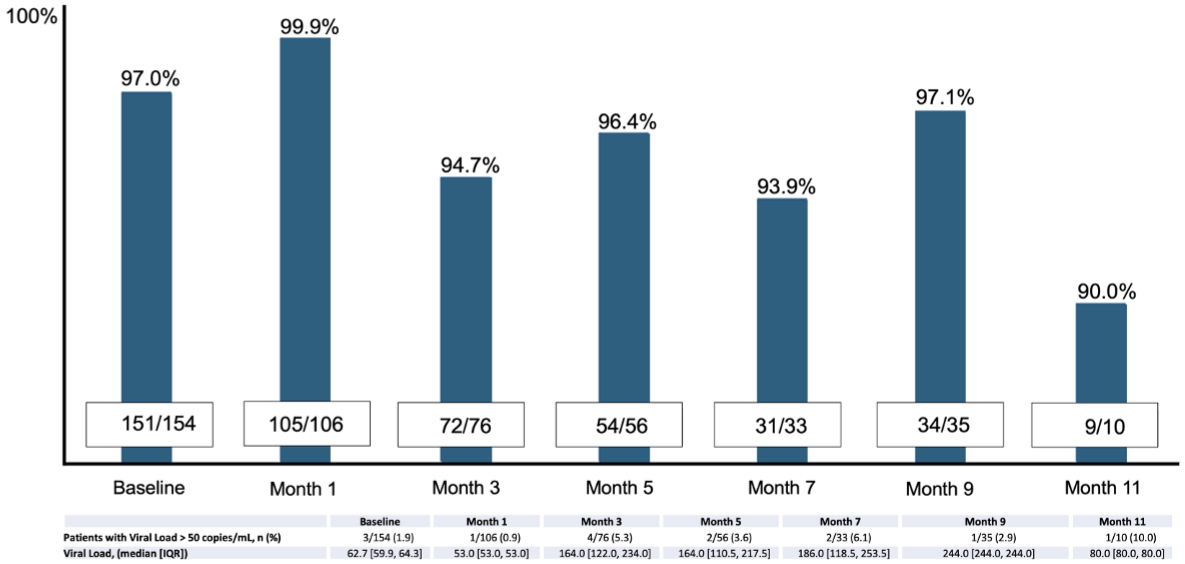

	Baseline	Month 1	Month 3	Month 5	Month 7	Month 9	Month 11
Patients with Viral Load > 50 copies/mL, n (%)	3/154 (1.9)	1/106 (0.9)	4/76 (5.3)	2/56 (3.6)	2/33 (6.1)	1/35 (2.9)	1/10 (10.0)
Viral Load, (median [IQR])	62.7 [59.9, 64.3]	53.0 [53.0, 53.0]	164.0 [122.0, 234.0]	164.0 [110.5, 217.5]	186.0 [118.5, 253.5]	244.0 [244.0, 244.0]	80.0 [80.0, 80.0]

Eficacia en 11 primeros meses

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Subestudio Mujeres. Cohorte RELATIVITY

RELATIVITY

HIV DRUG THERAPY GLASGOW 2024 P065

EFFICACY AND SAFETY OF LONG-ACTING INTRAMUSCULAR CABOTEGRAVIR AND RILPIVIRINE IN WOMEN: A SUBSTUDY OF THE RELATIVITY COHORT

María José Galindo Puerto[1], Noemí Cabello-Clotet[2], María Teresa Aldamiz-Echevarría Lois[3], Jara Llenas-García[4], Mari Mar Arcos[5], Ana Ferrer Ribera[1], Jesús Troya[6], Luis Buzón[7], Miguel Torralba[8], Mireia Santacreu[9], María Aguilera García[10], Alfonso Cabello Úbeda[11], María José Crusells Canales[12], Luis Morano[13], Roberto Pedrero Tomé[14], Patricia Martín Rico[15], Carmen Montero Hernández[16], Desirée Pérez Martínez[17], Sara de la Fuente[18], Ruth Calderón Hernaiz[19], Enrique Bernal[20], María Jesús Vivancos Gallego[21], María Antonia Sepúlveda[22], Álvaro Cecilio[23], Víctor Arenas García[24], Sergio Padilla[25], Juan Emilio Losa-García[26], Francisco Arnaiz de las Revillas Almajano[27], Antonio Jesús Sánchez Guirao[28], María del Mar García Navarro[29], Ana Cerezales Calviño[30], María Ángeles Garcinuño Jiménez[31], Ferreira Pasos Eva María[32], Miriam Estébanez[33], Beatriz de la Calle Riaguas[34], Miguel Egido Murciano[35], Noemí Ramos Vicente[36], Marta Clavero Olmos[37], Juan Manuel Tiraboschi[38], The RELATIVITY PROJECT GROUP

BACKGROUND

Intramuscular cabotegravir (CAB) and rilpivirine (RPV), administered every two months, can be used as a switching strategy in virologically suppressed people who live with HIV (PLWH). Women are underrepresented in clinical trials (1-3). Real-life data regarding efficacy and safety in this population are scarce. The aim of this substudy is to determine efficacy, tolerability and safety of this strategy when used to treat women who live with HIV (WLWH) in real life, out of a clinical trial context.

MATERIAL AND METHODS

The RELATIVITY cohort is a multicentre, non-controlled, ambispective study, which evaluates virologically supressed PLWH who switched to long-acting CAB+RPV from 37 hospitals in Spain (RELATIVITY Cohort). Patients were compared based on gender. Quantitative variables were contrasted using T-Student and U-Mann-Whitney tests; categorical variables were compared using Chi-Square and Fisher's Exact tests.

RESULTS

Of 1358 HIV-positive patients on CAB+RPV, 201 (14.8%) were women. Baseline characteristics compared to men are depicted in table 1.

Time on ART [13.0 (8.0, 20.0) vs. 9.0 (5.0, 13.5) years; p-value < 0.001], and length of undetectability before switching to CAB+RPV [96.0 (45.0, 147.0) months vs. 80.0 (40.0, 124.0) months; p-value = 0.058] were longer in women. Additionally, rate of virological failure (VF) prior to switching was higher compared to men (11.7% vs. 3.5%; p-value < 0.001).

	Women (N=201)	Men (N=1157)	p-value
Demographic data			
Age (years), median [IQR]	51.0 [42.0, 58.0]	44.0 [37.0, 53.4]	<0.001
Body Mass Index (Kg/m2), median [IQR]	23.6 [20.7, 28.0]	24.8 [22.4, 27.2]	0,226
Country of origin, n (%) Spain	129 (62.5)	822 (71.9)	0,067
Migrants	69 (34.8)	322 (28.1)	0,072
Latin America	37 (18.4)	260 (22.6)	0,213
Africa	12 (6.0)	13 (1.1)	<0.001
Transmission route			
Transmission route, n (%) GBMSM	0 (0.0)	814 (76.2)	-
HTX	133 (72.7)	108 (10.0)	<0.001
PWID	23 (12.6)	66 (6.3)	<0.001
Comorbidities			
Comorbidities, n (%) Hypertension	28 (13.9)	104 (9.0)	0,04
Peripheral vascular disease	4 (2.0)	5 (0.4)	0,041
Osteopenia/osteoporosis	29 (14.4)	51 (4.4)	<0.001
Psychiatric disorders	25 (12.4)	54 (6.1)	0,002
HIV Data			
CD4 nadir (cells/mm3), median [IQR]	249.5 [115.8, 380.8]	350.0 [210.0, 500.0]	<0.001
CD4/CD8, median [IQR] Baseline	1.1 [0.7, 1.5]	0.9 [0.7, 1.3]	0,001
CD4/CD8, median [IQR] End of period	1.1 [0.8, 1.4]	0.9 [0.7, 1.3]	<0.001
AIDS, n (%)	35 (19.2)	128 (11.7)	0,007

Table 1. Comparative baseline analysis of women and men living with HIV who switched to long acting CAB+RPV in the Relativity cohort in Spain. n(%) number (perc=ntage)
GBMSM= gays, bisexuals and other man who have sex with man; HTX: heterosexual; IQR: interquartile range; PID: people who inject drugs

Table 2: basal genotype

Figure 1: Reasons for switching to CAB+RPV LAI

Current follow-up period was shorter for women (7.2 [4.6, 9.6] months vs. 7.7 [5.1, 11.1] months; p-value = 0.051) and discontinuation rate (8.5% vs. 4.1%; p-value = 0.014) and rate of local adverse injection reactions were higher compared to men (3.5% vs. 1.1%; p value < 0.001). There were no differences in systemic side effects or VF development compared to men.

Figure 2: percentage of women and men living with HIV with VL<50 cp/ml during follow -up

Figure 3: Evolution CD4 (cel/mcl) in men and women during the follow-up

Figure 4: Reasons to change CAB+RPV in women and men during the study period

CONCLUSIONS

Although WLWH who switched to CAB+RPV had a worse profile regarding comorbidities and prevalence of AIDS, they do not seem to have a higher risk of VF compared to men, but discontinuation rate might be higher. A longer follow up is necessary to understand outcomes in this underrepresented and critical subpopulation of PLHIV treated with CAB+RPV.

References:
Cyrus PE, Rossi G, Hodges-Mameletzis I, Johnston R, Price HN, Hendel S. A Systematic Review of the Inclusion (or Exclusion) of Women in HIV Research: From Clinical Studies of Antimicrobials and Vaccines to Cure Strategies. J Acquir Immune Defic Syndr. 2019 Feb 1;80(2):145-154. doi: 10.1097/QAI.0000000000001942. PMID: 30281171
Rizzardini G, Castagna A, Cazanave C, et al. Efficacy, safety, and tolerability of switching to long-acting cabotegravir plus rilpivirine versus continuing fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide in virologically suppressed adults with HIV: 12-month results (SOLAR): a randomised, open-label, phase 3b, non-inferiority trial. Lancet HIV. 2021 Sep;8(9):e586-e597.

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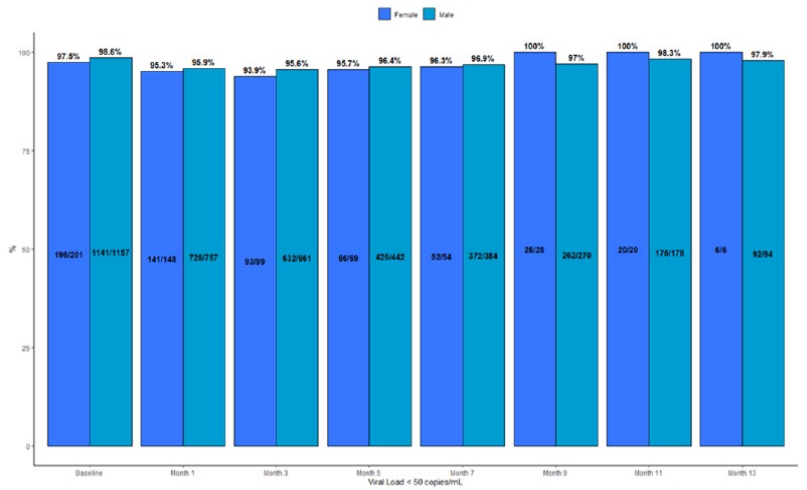

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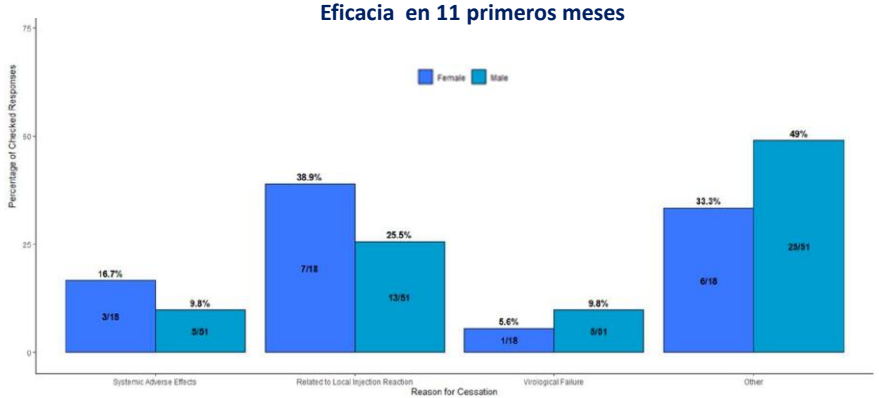

Motivos de retirada de CAB+ RPV

Mayor comorbilidad y estadio SIDA
Mayor tasa de retirada . Valorar factores

Buzón et al.Glasgow 2024

Subestudio Población Migrante. Cohorte RELATIVITY

RELATIVITY

HIV DRUG THERAPY GLASGOW 2024 P064

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

Jara Llenas-García[1], Roberto Pedrero Tomé[2], Luis Ramos Ruperto[3], María José Galindo Puerto[4], Mariano Matarranz del Amo[5], Carolina Navarro[6], Miguel Torralba[7], Mireia Santacreu[8], María Aguilera García[9], Alfonso Cabello Úbeda[10], Isabel San Joaquín Conde[11], Luis Enrique Morano[12], Noemí Cabello Clotet[13], Patricia Martín Ruiz[14], Carmen Montero Hernández[15], Elisa Pinto[16], Alberto Díaz de Santiago[17], Ruth Calderón Hernáez[18], Enrique Bernal[19], María Jesús Vivancos Gallego[20], María Antonia Sepúlveda[21], Chiara Fanciulli[22], Álvaro Cecilia[23], Josefa Soler González[24], Sergio Padilla[25], Juan Emilio Losa García[26], Carlos Astarloanzas Castillo[27], Antonio Jesús Sánchez Quirós[28], María del Mar García Navarro[29], Ana Cervantes Calvillo[30], María Ángeles Gacimartín Jiménez[31], Eva Estébanez[32], Miriam Ferreira Pasco[33], Beatriz de la Calle Raguas[34], Teresa Omede Samicente[35], Noemí Ramos Vicente[36], María Clavero Olmos[37], Juan Manuel Trabsoshi[38], Ana Lucas Dalo[39], on behalf of the RELATIVITY PROJECT GROUP

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.

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.

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.

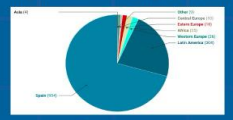

Figure 1. Area of origin of patients on CB+RPV in Relativity cohort

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

		Migrants (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 (0.29 - 2.58)	1.000
	F/CRF	6.3%	2.0%	3.26 (1.23 -	0.010

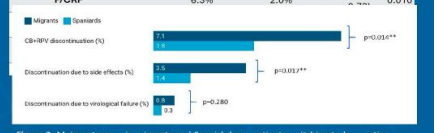

Figure 3. Main outcomes in migrants and Spanish-born patients switching to long-acting injectable CAB+RPV in the Relativity cohort . *CAB: cabotegravir; RPV: rilpivirine*

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.

RELATIVITY

Contact: jllenas@umh.es

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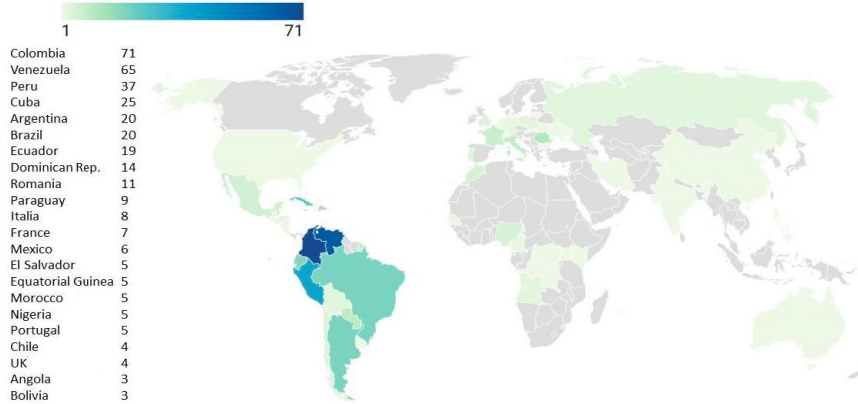
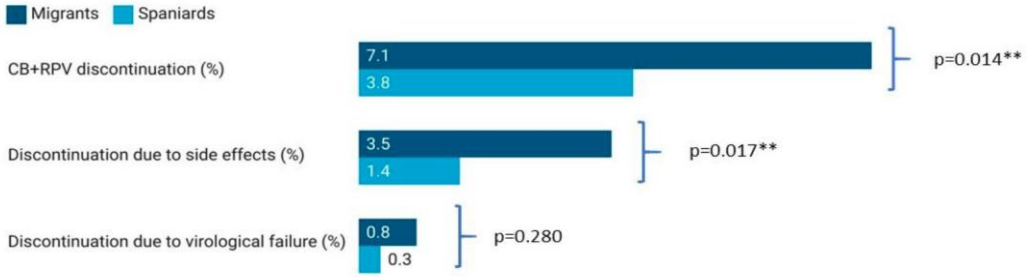
HIV DRUG THERAPY GLASGOW 2024

Number of patients from each country



Colombia	71	Germany	2
Venezuela	65	Belgium	2
Peru	37	Cameroon	2
Cuba	25	Costa Rica	2
Argentina	20	Nicaragua	2
Brazil	20	Netherlands	2
Ecuador	19	Senegal	2
Dominican Rep.	14	Australia	1
Romania	11	Bulgaria	1
Paraguay	9	China	1
Italia	8	Croatia	1
France	7	Slovakia	1
Mexico	6	USA	1
El Salvador	5	Philippines	1
Equatorial Guinea	5	Guatemala	1
Morocco	5	Haiti	1
Nigeria	5	India	1
Portugal	5	Iran	1
Chile	4	Kenia	1
UK	4	Lithuania	1
Angola	3	Moldova	1
Bolivia	3	DRC	1
Honduras	3	Switzerland	1
Poland	3	Ukraine	1
Rusia Fed.	3	Uganda	1
		Uruguay	1

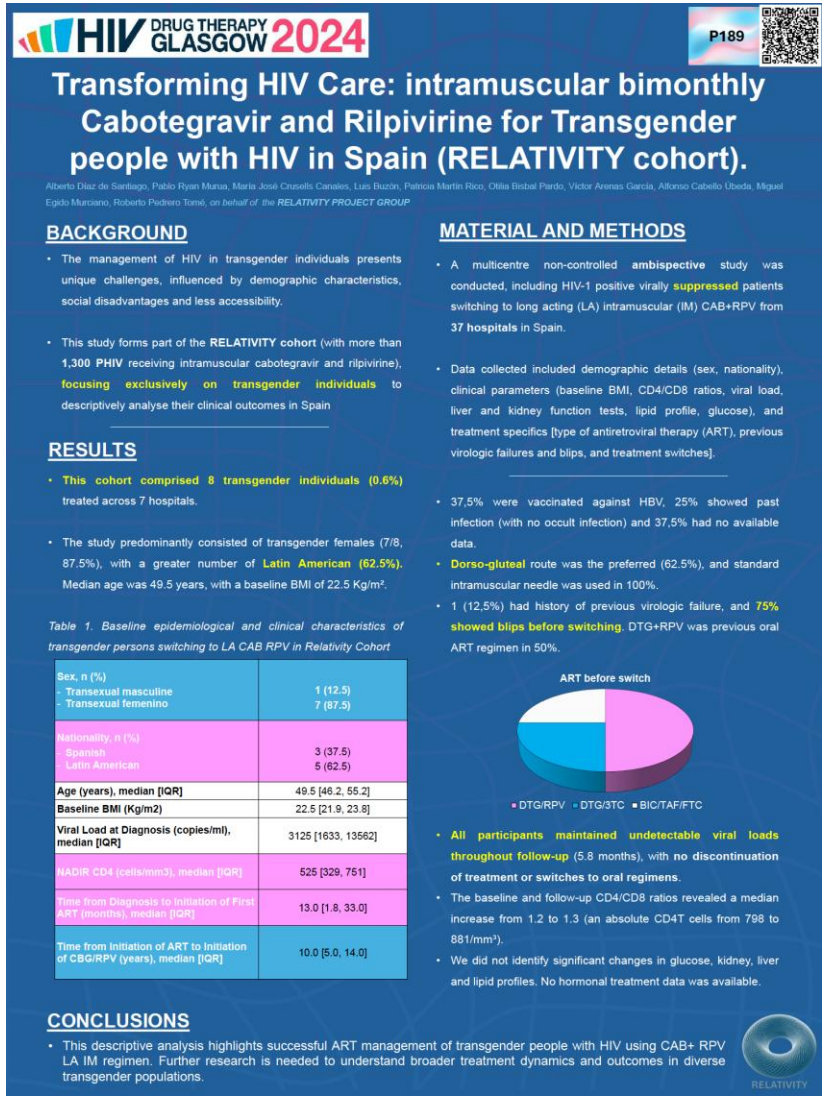


Tasa de discontinuaciones menor 1% por fracaso virológico

Llenas et al.Glasgow 2024

Subestudio Transgénero. Cohorte RELATIVITY

RELATIVITY



Sex, n (%) - Transexual masculine - Transexual femenino	1 (12.5) 7 (87.5)
Nationality, n (%) - Spanish - Latin American	3 (37.5) 5 (62.5)
Age (years), median [IQR]	49.5 [46.2, 55.2]
Baseline BMI (Kg/m2)	22.5 [21.9, 23.8]
Viral Load at Diagnosis (copies/ml), median [IQR]	3125 [1633, 13562]
NADIR CD4 (cells/mm3), median [IQR]	525 [329, 751]
Time from Diagnosis to Initiation of First ART (months), median [IQR]	13.0 [1.8, 33.0]
Time from Initiation of ART to Initiation of CBG/RPV (years), median [IQR]	10.0 [5.0, 14.0]

HIV DRUG THERAPY GLASGOW 2024

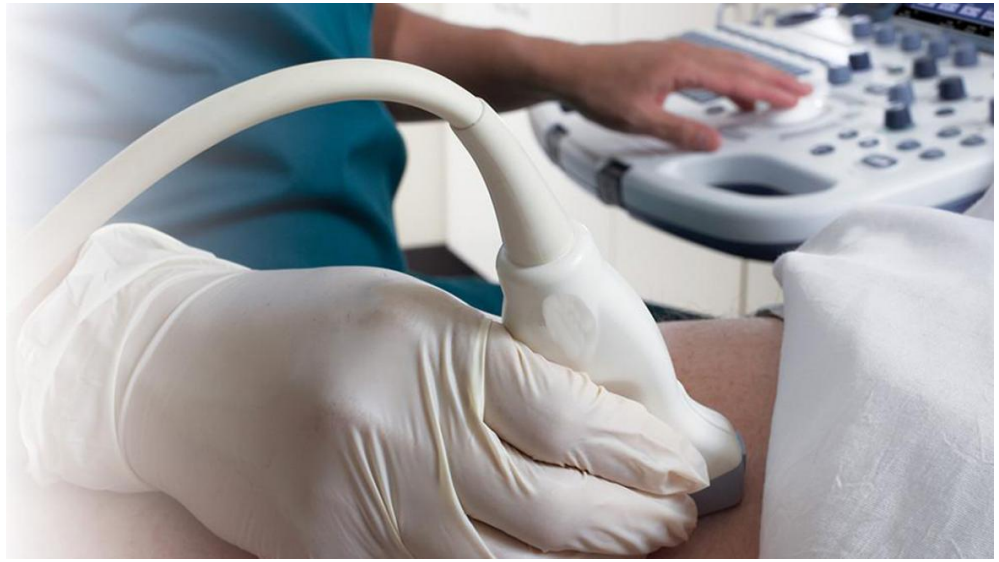
No discontinuaciones

No fracasos virológicos

Díaz de Santiago et al.Glasgow 2024

Papel de la Ecografía Clínica

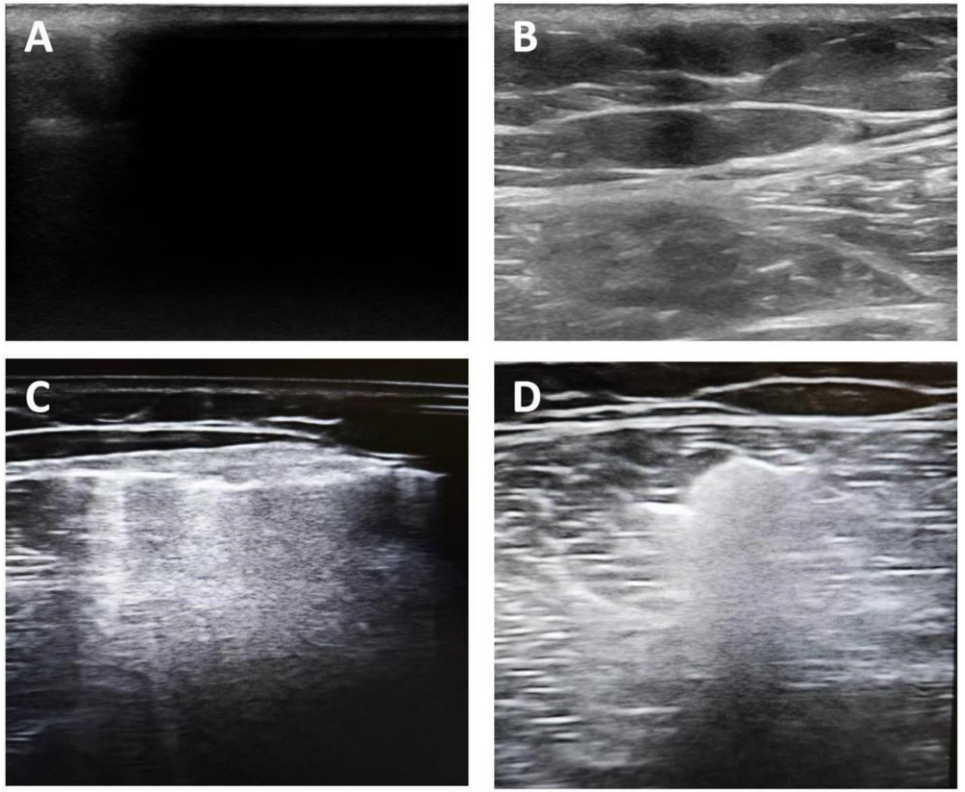
Journal of Antimicrobial Chemotherapy



J Antimicrob Chemother. 2025 Apr 21:dkaf127. doi: 10.1093/jac/dkaf127. Online ahead of print.

Ultrasound for long-acting injectable cabotegravir and rilpivirine in transgender individuals with implants: a new opportunity for normalization

Jesús Troya [1], Guillermo Cuevas [1], Mercedes Duffort [2], Miguel Ángel Casado [2], Mariano Matarranz [1]



Población Trasplantados. Cohorte H. Ramón y Cajal

HIV DRUG THERAPY GLASGOW 2024

P069

Long-Acting Cabotegravir/Rilpivirine as a Safe Antiretroviral Therapy in Solid Organ Transplanted HIV Patients

Ana Moreno[1], Santos del Campo[1], María Jesús Pérez-Elías[1], José Luis Casado[1], Miguel García[2], Manuel Vélez[3], María Jesús Vivancos[1], Santiago Moreno[1]
[1]Infectious Diseases, Hospital Ramón y Cajal, Madrid, Spain, Spain, [2]Gastroenterology (Liver Transplant Unit), Hospital Ramón y Cajal, Madrid, Spain,

Baseline Features

	P1	P2	P3	P4	P5
Type of transplant	Liver	Liver	Liver	Liver	Renal
Age (years)	60	61	49	59	61
Sex	Male	Female	Female	Male	Male
Race	White	White	White	White	Gypsy
CDC-Stage	C3	C3	B3	C3	B3
HIV Risk Factor	IDU	IDU	IDU	IDU	IDU
Years on ART	24	28	14	29	28
Years from transplantation to LA	5	10	12	6	1
Baseline BMI	22	21	38*	25	32*
CD4 (cells/ml)	856	575	767	347	583
HIV RNA (log_{10} copies/ml)	<1.30	<1.30	<1.30	<1.30	<1.3
GFR (ml/min)	76	32	91	85	24
HIV Subtype	Unavailable	Unavailable	Unavailable	Unavailable	Unavailable
Prior NNRTI experience	NVP No failure	NO	EFV, RPV No failure	NVP, ETRA, RPV No failure	EFV, RPV No failure
Number of prior ARV lines	7	6	8	11	22
Prior ARV	BIC/TAF/FTC	BIC/TAF/FTC	DTG/3TC	DTG/3TC/ABC	BIC/TAF/FTC

	P1	P2	P3	P4	P5
Reason for LA	Patient´s request	Medical proposal	Medical proposal	Medical proposal	Medical proposal
LA Start date	Sept, 27, 2023	Nov, 2, 2023	Nov, 6, 2023	Feb, 9, 2024	May, 20, 2024
HBV status	HBsAg NEGATIVE HBcAb + HBsAb +	HBsAg NEGATIVE HBcAb + HBsAb +	HBsAg NEGATIVE HBcAb + HBsAb +	HBsAb+ (vaccinated)	HBsAb+ (vaccinated)
Imunossupresive therapy	Everolimus	Cyclosporine Mycophenolate	Tacrolimus Mycophenolate	Everolimus Steroids	Cyclosporin Mycophenolate Steroids
Comorbidities	COPD Type 2 diabetes Dyslipidemia	Renal insufficiency	Depression Obesity Hypertension Dyslipidemia	HPV-related ORL carcinoma Hypertension Depression	Liver cirrhosis Type 2 diabetes Ischemic cardiopathy Hypertension Dyslipidemia
Concomitant therapies	Pantoprazole Aspirin Inh salbultamol Vildagliptin/metformin Atorvastatin D Vitamin	Pantoprazole Enalapril Clonazepam D Vitamin	Atorvastatin Lorazepam Enalapril Pregabalin D Vitamin Semaglutide*	Pantoprazole Candesartan Sildenafil Aspirin Lorazepam D Vitamin	Isosorbide mononitrate Eplerenone Verapamile Betahistine Losartan Ezetimibe Linagliptine Aspirin

Outcomes

	P1	P2	P3	P4	P5
Weeks on LA	57	52	51	38	23
LA-related AEs	Mild initial ISR	Moderate ISR	Mild ISR	Mild ISR	Dizzines
Discontinuation	NO	NO	NO	NO	NO
Last HIV RNA (log_{10} copies/ml)	<1.30	<1.30	<1.30	<1.30	<1.30
HIV RNA blips	NO	NO	NO	NO	NO
Last CD4 count (cells/ml)	782	563	1034	358	544
Last GFR (ml/min)	83	41	99	100	30
Last BMI	23	21	40	24	33

LA with C/R may be considered in SOT patients as a safe and effective ARV

Población Chemsex. Cohorte Hospital Clínic Barcelona

XV CONGRESO NACIONAL GRUPO DE ESTUDIO DEL SIDA GeSIDA 24 AL 27 NOVIEMBRE 2024 AUDITORIO DE ZARAGOZA ZARAGOZA WWW.CONGRESOGESIDA.COM

Eficacia de cabotegravir y rilpivirina de acción prolongada en poblaciones especiales: personas que practican chemsex

P013

Maria Martínez-Rebollar*, Lorena De La Mora, Montserrat Laguno, Leire Berrocal, Berta Torres, Ivan Chivite, Alexy Inciarte, Paula Arreba, Juan Ambrosioni, Alberto Foncillas, José Luis Blanco, Júlia Calvo, Esteban Martínez, Abiu Sempere, Pilar Callau, Josep M Miró, Roger Llobet, Elisa de Lazzari, Josep Mallolas, Ana González-Cordón. Enfermedades Infecciosas – Unidad de VIH, Hospital Clínic, Barcelona; IDIBAPS; Universidad de Barcelona; CIBERINFEC, ISC-III, Madrid. *rebollar@clinic.cat

Características basales de las personas que practican chemsex en el estudio de CAB/RPV-AP N=56

Edad, media (DE)	43 (8)
Sexo, hombre, n (%)	56 (100%)
Origen, n (%)	
España	20 (36%)
Migrante	36 (64%)
IMC >30 kg/m2, n (%)	2 (4%)
Años desde diagnóstico, mediana (RIC)	11 (8-16)
CV<50cp/mL, n (%)	54 (96%)
Tiempo con <50cp/mL, mediana años (RIC)	7.21 (4.07-10.95)
Últimos CD4, céls/microL, mediana (RIC)	706 (629-987)
CD4 nadir, céls/microL, mediana (RIC)	437 (354-572)
Genotipado histórico disponible, n (%)	29 (52%)
Cualquier mutación	6 (11%)
Años en TAR, mediana (RIC)	7.85 (4.44 -11.80)
Pauta de TAR previa basada en:	
IP	1 (2%)
NNRTI	6 (11%)
INSTI	38 (69%)
Fracaso virológico previo, n (%)	3
RIC: rango intercuartílico; IMC: Índice de masa corporal; CV: carga viral	

Figura 1. Frecuencia de uso de sustancias

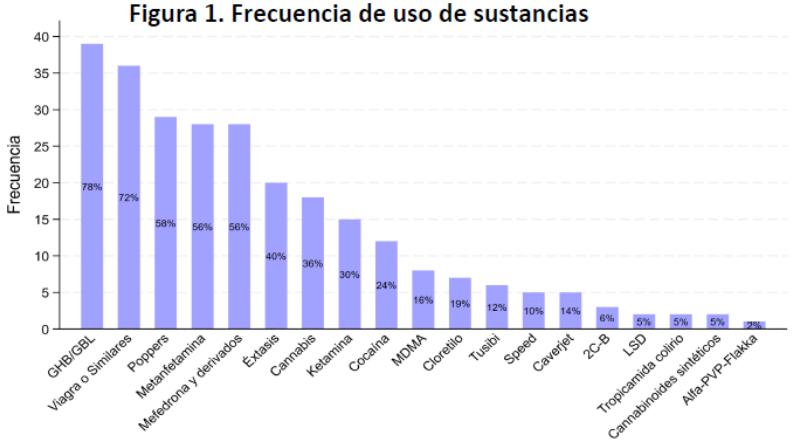
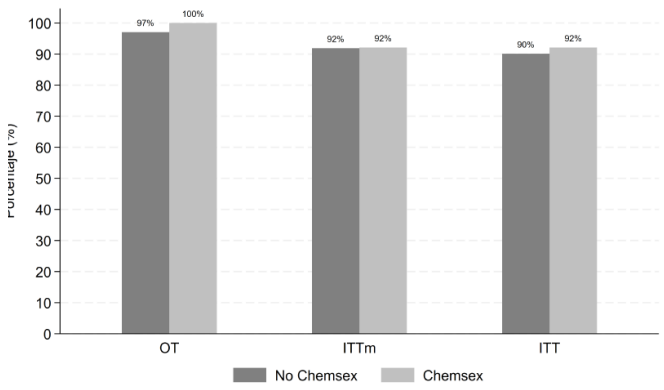


Figura 2. Efectividad en semana 28



Treinta y cinco personas alcanzaron la S28 y 20 la S52. La efectividad fue del 100%, 92% y 92% en S28, y del 100%, 91% y 91% en S52, según OT, ITTm y ITT, sin diferencias respecto a la cohorte general (Figura 2)*.

Un participante cumplió la definición de **fracaso virológico** (dos CV >50 copias/mL consecutivas). Se trató de un fracaso de bajo nivel y se decidió pasar a pauta oral basada en inhibidor de la proteasa potenciado.

El 95% de las inyecciones se administraron dentro de **ventana** y un 3% con retraso.

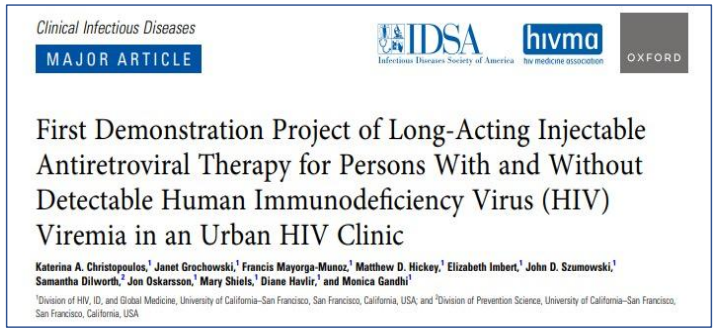
Poblaciones vulnerables

¿Es posible tratar con long acting de CAB+RPV a poblaciones vulnerables con mala adherencia y tener éxito?

¿Es posible cumplir los límites de administración del long-acting de CAB+RPV en poblaciones vulnerables con mala adherencia a consulta?

¿Hay diferencia en el long-acting CAB+RPV vs terapia oral en poblaciones vulnerables mal adherentes, en términos de fracaso?

Éxito de tratamiento



Clinical Infectious Diseases

MAJOR ARTICLE

First Demonstration Project of Long-Acting Injectable Antiretroviral Therapy for Persons With and Without Detectable Human Immunodeficiency Virus (HIV) Viremia in an Urban HIV Clinic

Katerina A. Christopoulos,[1] Janet Grochowski,[1] Francis Mayorga-Munoz,[1] Matthew D. Hickey,[1] Elizabeth Imbert,[1] John D. Szumowski,[1] Samantha Dilworth,[2] Jon Oskarsson,[1] Mary Shiels,[1] Diane Havlir,[1] and Monica Gandhi[1]

[1]Division of HIV, ID, and Global Medicine, University of California–San Francisco, San Francisco, California, USA; and [2]Division of Prevention Science, University of California–San Francisco, San Francisco, California, USA

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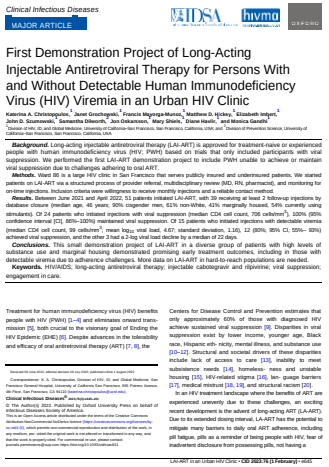
Demonstration Project of Long-Acting Antiretroviral Therapy in a Diverse Population of People With HIV

Monica Gandhi, MD, MPH,
Division of HIV, Infectious Diseases and Global Medicine, Department of Medicine, University of California, San Francisco, San Francisco, California



Clinical Infectious Diseases

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Background. Long-acting injectable antiretroviral therapy (LA-ART) is approved for treatment-naive or experienced people with human immunodeficiency virus (HIV, PWH) based on trials that only included participants with viral suppression. We performed the first LA-ART demonstration project to include PWH unable to achieve or maintain viral suppression due to challenges adhering to oral ART.

Methods. Ward 86 is a large HIV clinic in San Francisco that serves publicly insured and underinsured patients. We started patients on LA-ART via a structured process of provider referral, multidisciplinary review (MD, RN, pharmacist), and monitoring for on-time injections. Inclusion criteria were willingness to receive monthly injections and a reliable contact method.

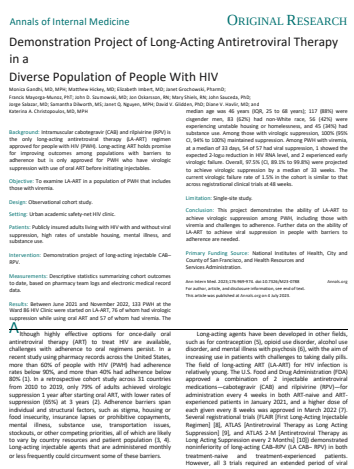
Results. Between June 2021 and April 2022, 51 patients initiated LA-ART, with 39 receiving at least 2 follow-up injections by database closure (median age, 46 years; 90% cisgender men, 61% non-White, 41% marginally housed, 54% currently using stimulants). Of 24 patients who initiated injections with viral suppression (median CD4 cell count, 706 cells/mm^3), 100% (95% confidence interval [CI], 86%–100%) maintained viral suppression. Of 15 patients who initiated injections with detectable viremia (median CD4 cell count, 99 cells/mm^3; mean $\log_{10}$ viral load, 4.67; standard deviation, 1.16), 12 (80%; 95% CI, 55%– 93%) achieved viral suppression, and the other 3 had a 2-log viral load decline by a median of 22 days.

Conclusions. This small demonstration project of LAI-ART in a diverse group of patients with high levels of substance use and marginal housing demonstrated promising early treatment outcomes, including in those with detectable viremia due to adherence challenges. More data on LA-ART in hard-to-reach populations are needed.

Keywords. HIV/AIDS; long-acting antiretroviral therapy; injectable cabotegravir and rilpivirine; viral suppression; engagement in care.

Treatment for human immunodeficiency virus (HIV) benefits people with HIV (PWH) [1–4] and eliminates onward transmission [5], both crucial to the visionary goal of Ending the HIV Epidemic (EHE) [6]. Despite advances in the tolerability and efficacy of oral antiretroviral therapy (ART) [7, 8], the Centers for Disease Control and Prevention estimates that only approximately 60% of those with diagnosed HIV achieve sustained viral suppression [9]. Disparities in viral suppression exist by lower income, younger age, Black race, Hispanic eth- nicity, mental illness, and substance use [10–12]. Structural and societal drivers of these disparities include lack of access to care [13], inability to meet subsistence needs [14], homeless- ness and unstable housing [15], HIV-related stigma [16], lan- guage barriers [17], medical mistrust [18, 19], and structural racism [20].

In an HIV treatment landscape where the benefits of ART are experienced unevenly due to these challenges, an exciting recent development is the advent of long-acting ART (LA-ART). Due to its extended dosing interval, LA-ART has the potential to mitigate many barriers to daily oral ART adherence, including pill fatigue, pills as a reminder of being people with HIV, fear of inadvertent disclosure from possessing pills, not having a



Annals of Internal Medicine ORIGINAL RESEARCH

Demonstration Project of Long-Acting Antiretroviral Therapy in a Diverse Population of People With HIV

Although highly effective options for once-daily oral antiretroviral therapy (ART) to treat HIV are available, challenges with adherence to oral regimens persist. In a recent study using pharmacy records across the United States, more than 60% of people with HIV (PWH) had adherence rates below 90%, and more than 40% had adherence below 80% (1). In a retrospective cohort study across 31 countries from 2010 to 2018, only 79% of adults achieved virologic suppression 1 year after starting oral ART, with lower rates of suppression (65%) at 3 years (2). Adherence barriers span individual and structural factors, such as stigma, housing or food insecurity, insurance lapses or prohibitive copayments, mental illness, substance use, transportation issues, stockouts, or other competing priorities, all of which are likely to vary by country resources and patient population (3, 4). Long-acting injectable agents that are administered monthly or less frequently could circumvent some of these barriers.

Long-acting agents have been developed in other fields, such as for contraception (5), opioid use disorder, alcohol use disorder, and mental illness with psychosis (6), with the aim of increasing use in patients with challenges to taking daily pills. The field of long-acting ART (LA-ART) for HIV infection is relatively young. The U.S. Food and Drug Administration (FDA) approved a combination of 2 injectable antiretroviral medications—cabotegravir (CAB) and rilpivirine (RPV)—for administration every 4 weeks in both ART-naive and ART-experienced patients in January 2021, and a higher dose of each given every 8 weeks was approved in March 2022 (7). Several registrational trials (FLAIR [First Long-Acting Injectable Regimen] [8], ATLAS [Antiretroviral Therapy as Long Acting Suppression] [9], and ATLAS 2-M [Antiretroviral Therapy as Long Acting Suppression every 2 Months] [10]) demonstrated noninferiority of long-acting CAB–RPV (LA CAB– RPV) in both treatment-naive and treatment-experienced patients. However, all 3 trials required an extended period of viral

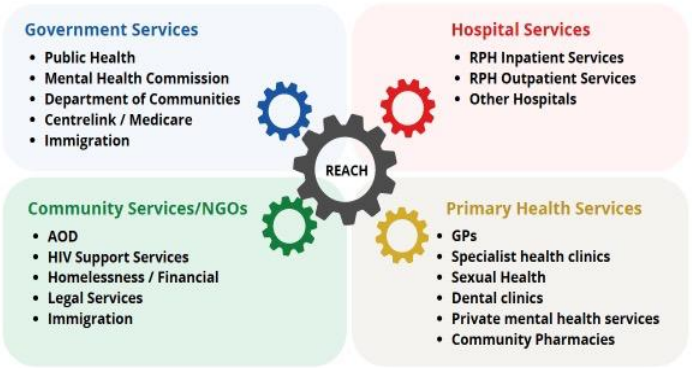
Oskarsson J, et al. Clin Infect Dis. 2023 Feb 8;76(3):e645-e651. doi: 10.1093/cid/ciac631

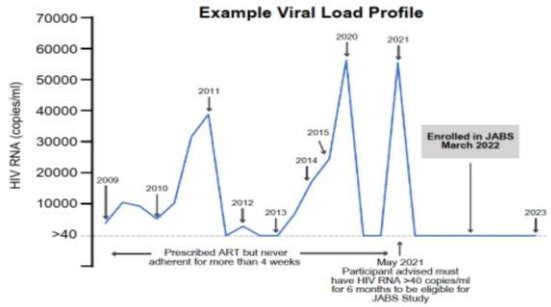
Gandhi M, et al. Ann Intern Med. 2023 Jul;176(7):969-974 doi: 10.7326/M23-0788.

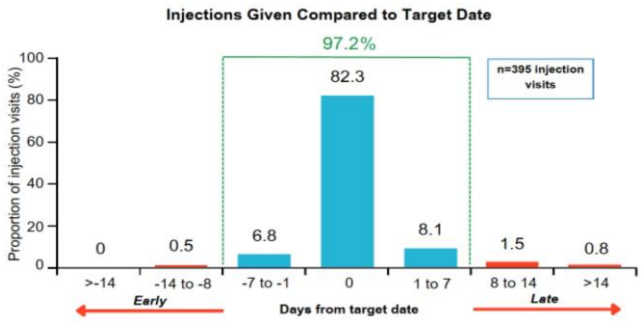
Adherencia a Visitas

JABS 48 week results: Implementation of long-acting cabotegravir and rilpivirine in vulnerable populations with complex needs

Mina John[1,2*], Leah Williams[1], Genevieve Nolan[1], Morgan Bonnett[1], Ailsa Allen[1], Alison Castley[1,2], David Nolan[1]
[1] Department of Clinical Immunology, Royal Perth Hospital, Western Australia
[2] PathWest, WA Health, Western Australia
*Corresponding author: Mina.John@health.wa.gov.au







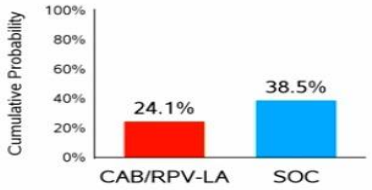
IAS 2023
July 23rd - 26th
12th IAS Conference on HIV Science

Alternativa a medicación oral

Primary Outcome

Regimen Failure

Difference	Nominal 98.75% CI
-14.5%	(-29.8%, 0.8%)



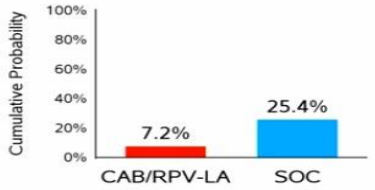
Number of participants

	CAB/RPV-LA	SOC
Regimen Failure	28	47
VF	5	28
TRT-DISC	23	19

Secondary Outcomes

Virologic Failure

Difference	Nominal 98.75% CI
-18.2%	(-31.1%, -5.4%)

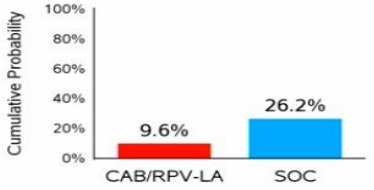


Number of participants

	CAB/RPV-LA	SOC
Virologic Failure	6	28

Treatment-related Failure

Difference	Nominal 98.75% CI
-16.6%	(-29.9%, -3.3%)

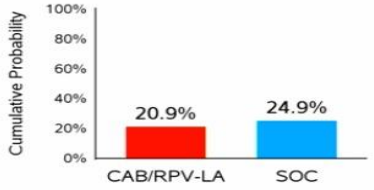


Number of participants

	CAB/RPV-LA	SOC
Treatment-related Failure	9	29
VF	6	28
TRT-DISC (AE)	3	1

Permanent Treatment Discontinuation

Difference	Nominal 98.75% CI
-4.1%	(-18.0%, 9.8%)



Number of participants

	CAB/RPV-LA	SOC
Permanent TRT-DISC	25	30

LATITUDE

ACTG

OTROS

Subestudio DTG/RPV. Cohorte RELATIVITY

RELATIVITY

HIV DRUG THERAPY GLASGOW 2024 P104

SWITCHING TO LONG ACTING INTRAMUSCULAR CABOTEGRAVIR AND RILPIVIRINE IN VIROLOGICALLY SUPPRESSED PLHIV TREATED WITH DOLUTEGRAVIR/RILPIVIRINE. A SUBESTUDY FROM THE RELATIVITY COHORT

María José Galindo Puerto, Luis Buzón Martín, Jesús Troya, Luz Martín Carbonero, Laura Bermejo Plaza, Miguel Torralba, Carmen Montero Hernández, Miguel Alberto de Zárraga Fernández Roberto Pedrero-Tomé, Noemí Cabello Clotet, Víctor Arenas García, Javier García Abellán, Alfonso Cabello Úbeda, Juan Emilio Losa García, María José Crusells Canales, Jara Llenas García, Beatriz De la Calle Riaguas, Luis Morano, María Aguilera García, Patricia Martín Rico, Enrique Bernal, Sara de la Fuente, Ruth Calderón Hernáiz, María Antonia Sepúlveda, Marouane Mencht, Marta Olmo Claveros, Manuel Gutiérrez Cuadra, Miriam Estebanez, Bárbara Alonso Moreno, Álvaro Cecilio, Miguel Egido Murciano, Guillermo Cuevas Tascón, on behalf of the RELATIVITY PROJECT GROUP

BACKGROUND

Cabotegravir and Rilpivirine (CAB+RPV) is the first long-acting injectable (LAI) treatment approved for people living with HIV (PLWH). It is indicated in patients with undetectable viral load, without evidence or suspected resistance to CAB+RPV. Dolutegravir/Rilpivirine (DTG+RPV) is similar to CAB+RPV and has been used in real life as oral lead-in before starting LAI.

MATERIAL AND METHODS

The RELATIVITY cohort is a multicentre, non-controlled, ambispective study on HIV virologically suppressed individuals who switched to LAI CAB+RPV. We analysed the characteristics of the patients who were on treatment with DTG+RPV prior to the switch. Additionally, patients were compared based on prior knowledge of their genotype. Quantitative variables were contrasted using T-Student and U-Mann-Whitney tests; categorical variables were compared using Chi-Square and Fisher's Exact tests.

RESULTS

A total of 313 individuals from 30 hospitals in Spain were analysed, representing 22.9% of the Relativity cohort, which comprised 1366 individuals. Median follow-up was 7.9 [IQR:5.2-11.5] months. 83.3% were male. The most common transmission route was GBMSM (57.8%), followed by HTX (24.9%). AIDS prevalence was 11.4%. The most frequent comorbidities were dyslipidaemia (24.3%), hypertension (9.3%), and psychiatric disorders (8.3%). Previous genotyping was available in 44.4% (134/313) of cases: 13/134 presented NNTRI mutations. Patients with known genotype tended to be younger (46.2 [40.0, 54.0] vs. 49.8 [40.0, 58.0]; p-value = 0.080) and Spanish instead of foreigners (84.3% vs 70.7%, p-value = 0.009). Prior virological failure (VF) was more common when previous genotype was available (8.5% vs. 5.5%; p-value = 0.029). Time on ART was similar on both groups (11.0 [8.0 - 17.0] years on ART). Patients decided to switch regimens for convenience or improve quality of life (52.1%), personal request (28.4%), simplification (25.9%), and malabsorption (8.0%) [more frequent reason (12.7%) among patients with known genotype (p-value = 0.023)]. Eleven patients discontinued treatment: two due to systemic adverse effects and only one due VF (known genotype group).

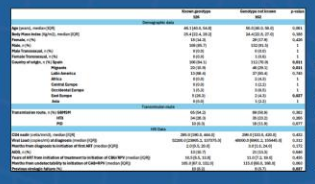


Table 1:Comparative analysis of the baseline characteristics of patients living with HIV on treatment with DTG+RPV who switched to CAB+RPV LAI with or without data of previous genotype

Table 2. basal genotype

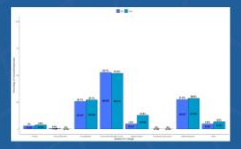


Figure 1:- Reasons for switching to CAB+RPV

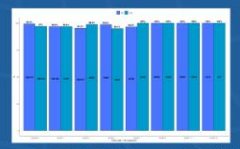


Figure 2: percentage of patients with and without previous genotype with VL <50 c/ml during follow-up

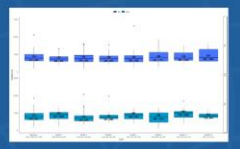


Figure 3: evolution of CD4 during the follow-up

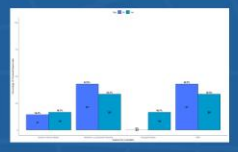


Figure 4: reasons to switch from CAB+RPV LAI to other options in patients with or without previous genotype

Not genotype available; no: no genotype

CONCLUSIONS

In real life settings, switching from DTG+RPV to CAB+RPV is safe and well tolerated. Our results suggest that in virologically suppressed PLHIV under treatment with DTG/RPV, previous genotyping results might not be necessary in order to switch to CBG/RPV

RELATIVITY

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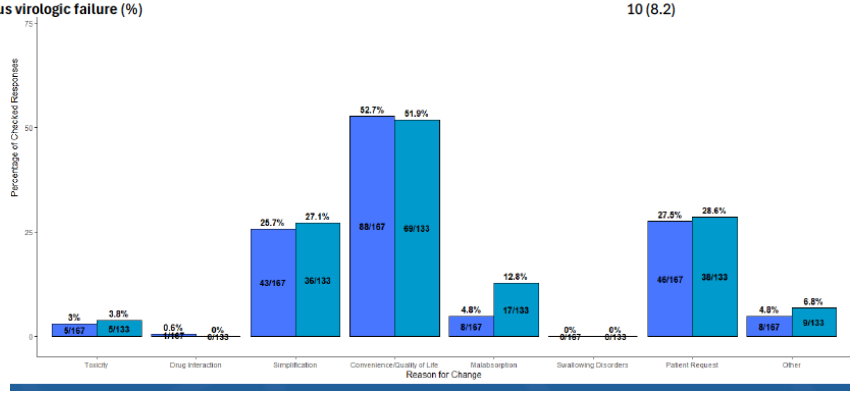
	Known genotype 126	Genotype not known 162	p-value
Demographic data			
Age (years), median [IQR]	46.1 [40.0, 54.8]	50.0 [40.0, 58.0]	0,061
Body Mass Index (Kg/m2), median [IQR]	25.4 [22.4, 28.2]	24.4 [22.8, 27.0]	0,188
Female, n (%)	18 (14.3)	29 (17.9)	0,426
Male, n (%)	108 (85.7)	132 (81.5)	1
Male Transsexual, n (%)	0 (0.0)	0 (0.0)	1
Female Transsexual, n (%)	0 (0.0)	1 (0.6)	1
Country of origin, n (%) **Spain**	106 (84.1)	112 (70.9)	**0,011**
Migrants	20 (15.9)	46 (29.1)	**0,011**
Latin America	13 (68.4)	37 (80.4)	0,745
Africa	0 (0.0)	2 (4.3)	1
Central Europe	0 (0.0)	1 (2.2)	1
Occidental Europe	1 (5.3)	3 (6.5)	1
East Europe	5 (26.3)	2 (4.3)	**0,027**
Asia	0 (0.0)	1 (2.2)	1
Transmission route			
Transmission route, n (%) **GBMSM**	65 (54.2)	89 (58.9)	0,382
HTX	34 (28.3)	35 (23.2)	0,265
PID	10 (8.3)	18 (11.9)	0,677
HIV Data			
CD4 nadir (cells/mm3), median [IQR]	295.0 [190.0, 444.0]	299.0 [133.0, 420.0]	0,432
Viral Load (copies/ml) **at diagnosis** (median [IQR])	52200.0 [23905.2, 137375.0]	48000.0 [6961.2, 155445.0]	0,312
Months from diagnosis to initiation of first ART (median [IQR])	2.0 [0.5, 20.0]	3.0 [1.0, 24.0]	0,172
AIDS, n (%)	13 (10.7)	21 (13.3)	0,646
Years of ART from initiation of treatment to initiation of CBG/RPV (median [IQR])	10.5 [8.5, 13.8]	11.0 [7.2, 19.0]	0,435
Months from undetectability to initiation of CAB+RPV (median [IQR])	105.0 [67.0, 132.0]	115.0 [68.0, 168.0]	0,063
Previous virologic failure (%)	10 (8.2)	9 (5.7)	**0,037**



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Clinical Infectious Diseases

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Clinical Infectious Diseases

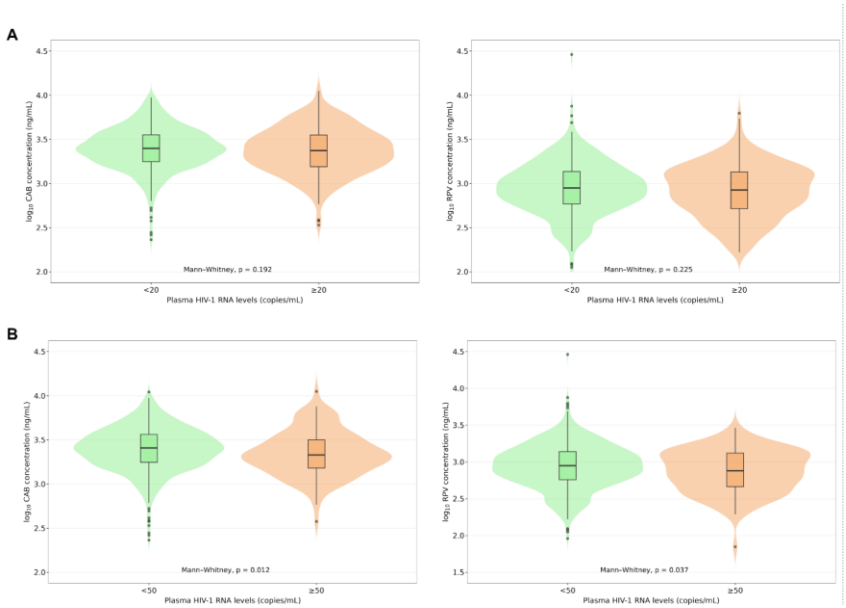
MAJOR ARTICLE

Virological History Predicts Non-sustained Viral Suppression with Long-Acting Cabotegravir and Rilpivirine Therapy, independent of Pharmacokinetic Parameters

Félix Gutiérrez [1,2,3,*], Marta Fernández-González [1,3], Christian Ledesma[1], María Losada-Echeberría[4], Enrique Barrajón-Catalán[4], Javier García-Abellán[1,2,3], Daria De Stefano[1], [2,3] and Mar Masiá[1,2,3].

	Any plasma HIV-1 RNA ≥20 copies/mL HR (95% CI) [P Value]					
	All participants (N=171) [a]			Participants switching to CAB+RPV with HIV-1 RNA <20 copies/mL (N=147)		
	Un-adjusted	Adjusted (N=122) [b]	Adjusted (N=122) [b]	Un-adjusted	Adjusted (N=104) [b]	Adjusted (N=104) [b]
HIV-1 viral load at diagnosis, log10 copies/mL	**1.59 (1.17-2.16) [.003]**	**1.49 (1.04-2.12) [.027]**	**1.48 (1.07-2.05) [.019]**	**1.59 (1.12-2.28) [.009]**	**1.67 (1.07-2.61) [.022]**	**1.62 (1.08-2.45) [.019]**
Episodes of detectable viremia within the prior year [c]: yes/no	**3.03 (1.75-5.24) [<.001]**	**2.45 (1.29-4.65) [.006]**	– [d]	**2.91 (1.59-5.32) [<.001]**	**2.17 (1.08-4.38) [.029]**	– [d]
Fully suppressed at the time of switching [e]: yes/no	**0.30 (0.17-0.53) [<.001]**	– [d]	**0.38 (0.19-0.75) [.004]**	**0.33 (0.18-0.60) [<.001]**	– [d]	0.72 (0.34-1.53) [.400]
Nadir CD4 cell count, cells/µL	0.98 (0.61-1.56) [.925]	– [d]	– [d]	0.87 (0.53-1.42) [.577]	– [d]	– [d]
Nadir CD4 cell count >350 cells/µL	Ref	– [d]	– [d]	Ref	Ref	Ref
Nadir CD4 cell count 200-350 cells/µL	0.99 (0.52-1.87) [.966]	– [d]	– [d]	1.59 (0.75-3.41) [.226]	2.05 (0.85-4.99) [.110]	2.09 (0.85-5.11) [.105]
Nadir CD4 <200 cells/µL	1.49 (0.82-2.70) [.183]	– [d]	– [d]	1.99 (0.94-4.22) [.070]	1.48 (0.59-3.64) [.395]	1.66 (0.68-4.09) [.264]
RPV-associated mutations in historical medical records: yes/no	1.10 (0.38-3.12) [.864]	– [d]	– [d]	1.70 (0.64-4.49) [.285]	– [d]	– [d]

Predictores de no RVS

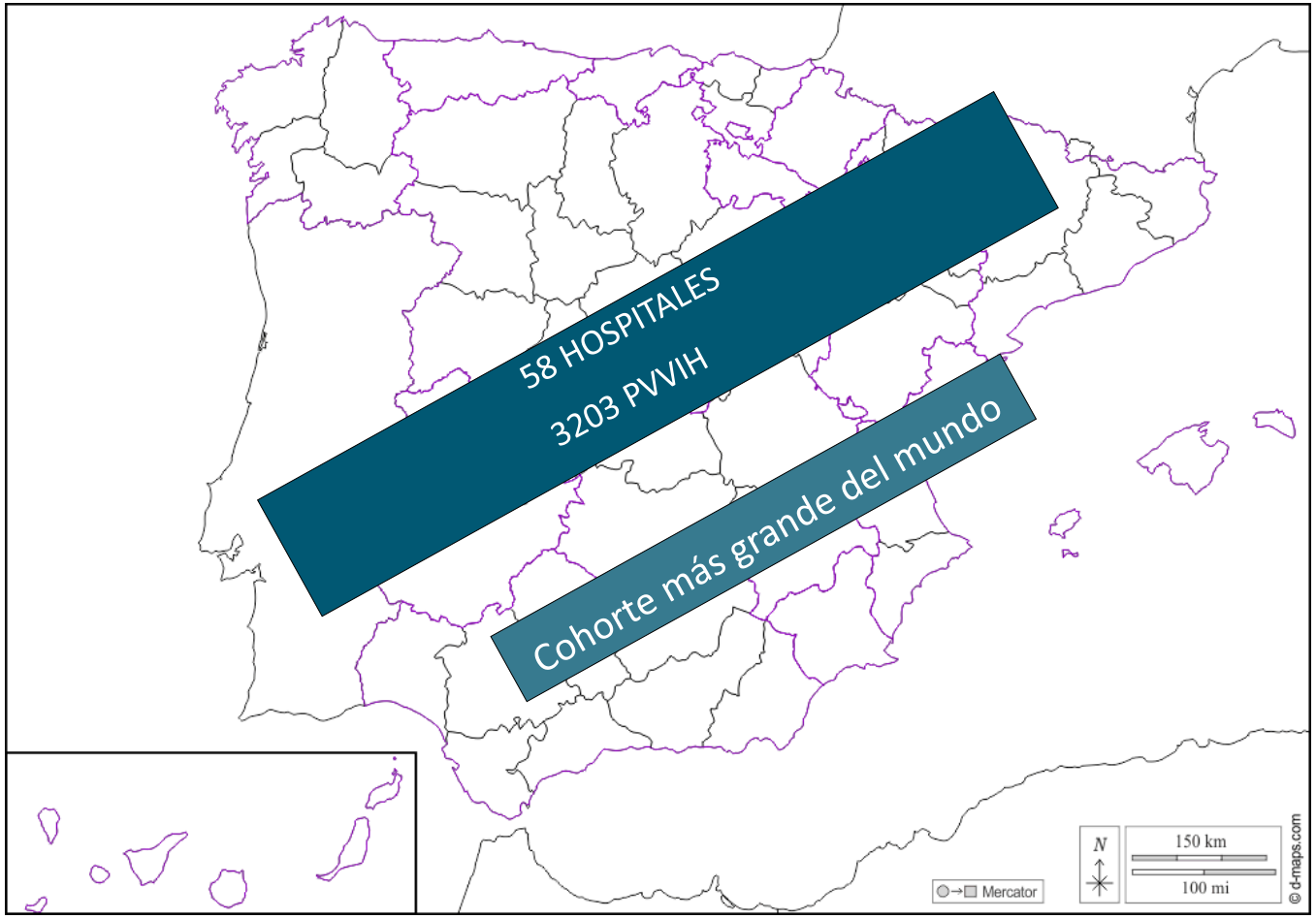


Concentraciones de CAB y RPV y CV detectable

Clin Infect Dis. 2024 Sep 19:ciae475. doi: 10.1093/cid/ciae475

Cohorte Relativity 2025

RELATIVITY



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