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REAL WORLD OUTCOMES OF CABOTEGRAVIR AND RILPIVIRINE FOR TREATING PLHIV IN SPAIN: A MULTICENTRE, AMBISPECTIVE AND NATIONWIDE STUDY (THE RELATIVITY COHORT)

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BACKGROUND

Randomized clinical trials and several real-life cohorts have provided evidence regarding non-inferiority of long-acting (L.A) intramuscular cabotegravir (CAB) and rilpivirine (RPV) compared to standard oral ART. In this context, the RELATIVITY cohort aims to evaluate the efficacy, safety and durability of L.A CAB and RPV in Spain, where these drugs are available since December 2022.

MATERIAL AND METHODS

The RELATIVITY cohort is an ambispective cohort which evaluates PLHIV treated at 37 Spanish hospitals. All PLHIV older than 18 years who received the first dose of treatment outside a clinical trial context were included (either retrospectively or at the time of starting treatment) after signing an informed consent and prospectively followed-up. No definition of virological failure or a concrete follow up pattern were imposed to investigators, atempting to reflect heterogeneity in clinical practice. Data gathered at April 1st 2024 are presented.

RESULTS

As of April 1st 2024, 1418 PLHIV had been recruited, and 1285 included in the analysis (90,6%,table 1). 85,7% were male, median age was 45 (37-54) years and 71,3% were spanish. 5.6% underwent oral leading. 88.6% switched from 2nd generation INSTI based regimens [DTG (67.4%) and BIC (21.2%)], with backbones consisting primarily of FTC/TAF (28.6%), 3TC (44.1%) and RPV (23.3%) and 7.4% from TAF/FTC/RPV. (figure 1). At baseline, 1.7% of patients were viremic. CD4 nadir was 339.0 [195.0, 484.0]. 13% had developed AIDS. Baseline CD4+ count was 774.0 [591.5, 999.5]. Median follow-up was 7.6 [5 – 11] months. Undetectable viral load ranged between 95.5% and 100% throughout the entire follow-up period (figure 2). 65 people discontinued treatment, (table 1), and six did it because of virological failure (table 2), with RAMs detected in three of them. Two of the patients who failed were screening failures. Other reasons for discontinuation included local injection site reactions (20) and systemic adverse effects (8) .

	N = 1285
Age (years) (median [IQR])	45.0 [37.0, 54.0]
Sex, n (%)	
Female	183 (14.3)
Male	1096 (85.7)
Transgender Male	1 (0.1)
Transgender Female	5 (0.5)
Nationality, n (%)	
Spanish	902 (71.3)
Migrants	368 (29.0)
CD4 nadir (cells/mm3), median [IQR]	339.0 [199.0, 488.0]
HIV diagnosis viral load (copies/ml) (median [IQR])	57999.0 [15900.0, 196020.0]
Months from diagnosis to start of first ART (median [IQR])	2.0 [1.0, 14.0]
AIDS, n (%)	161 (12.5)
Years of ART from treatment start to beginning of CBG/RPV (median [IQR])	9.0 [6.0, 14.0]
Months of undetectability until start of CAB+RPV (median [IQR])	81.0 [40.0, 130.0]
Previous virological failure on any ART regimen (%)	58 (4.5)
Which third drug was involved in the failure?, n (%)	
INI	16 (1.3)
NNRTI	13 (1.0)
PIs	20 (1.6)
Not available	9 (0.7)
Number of BLIPS in the 5 years prior to CBG/RPV treatment, n (%)	
0	1008 (80.8)
1	157 (12.6)
2	42 (3.4)
3	20 (1.6)
More than 3	21 (1.7)
Baseline genotipying previous to switch, n (%)	675 (52.5)
Subtype B	312 (24.3)
Subtype A1/A2	21 (1.6)
Subtype F/CRF	21 (1.6)
Other subtypes	37 (2.9)
Not available	284 (22.1)
Wild type without mutations, n (%)	451/675 (61.5)
PLHIV harbouirng virus with RAMs to NRTI, n (%)	63/675 (9.3)
184V	13/675 (1.9)
Others	65/675 (9.6)
PLHIV harbouirng virus with RAMs to NNRTI, n (%)	63/675 (9.3)
K103N	18/675 (2.7)
E138A	3/675 (0.4)
Others	37/675 (5.5)
PLHIV harbouirng virus with RAMs to INSTI, n (%)	5/675 (0.7)
L74M/I/F	1/675 (0.1)
T97A	2/675 (0.3)
Others	7/675 (1.0)
Treatment discontinuation, n (%)	65 (5.1)
Days of treatment discontinuation (median [IQR])	153.5 [81.8, 259.2]
Systemic adverse effects, n (%)	8 (5.1)
Related to local injection site reaction, n (%)	20 (1.6)
Virological failure, n (%)	6 (0.5)
Other, n (%)	31 (2.4)
Type of toxicity, n (%)	
Dizziness	0 (0.0)
Headache	1 (12.5)
Dysthermia	0 (0.0)
Fever	3 (37.5)
Nausea	0 (0.0)
Others	4 (50.0)

Table 1: Basal characteristics of the cohort

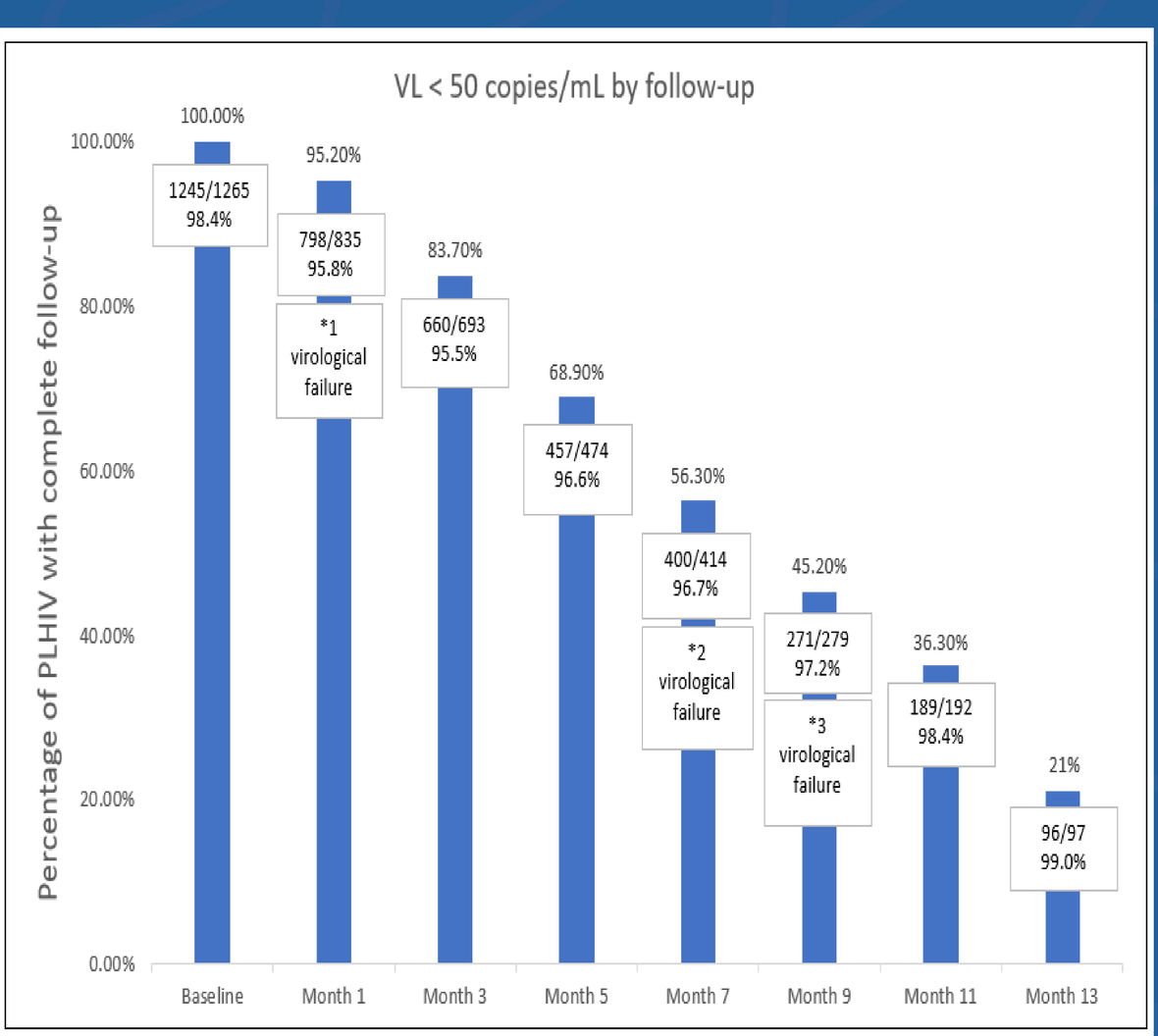

Figure 2: Percentage of PLHIV with VL<50 copies throughout different follow up periods

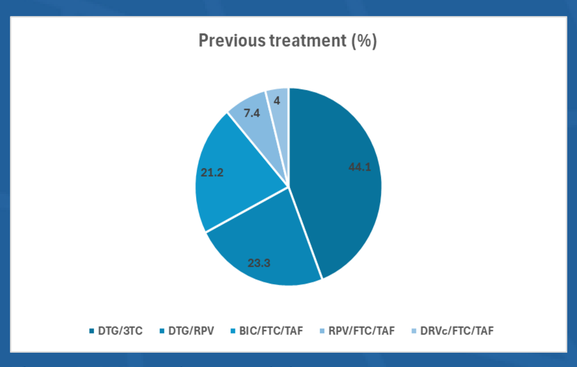

Figure 1: ART previous to switch

	1	2*	3	4**	5	6***
Sex	Male	Male	Male	Male	Female	Male
Age (years)	49	45	40	50	52	49
Body Mass Index (Kg/m^2)	22.5	29.3	24.3	33.9	36.3	27.5
Previous treatment	BIC/FTC/TAF	DTG/3TC	DTG/3TC	DTG/3TC	DTG/RPV	BIC/FTC/TAF
Month of discontinuation	7	7	9	9	1	9
Viral Load at discontinuation	3140	44000	289	128000	362	217
Previous mutations	Wild type without mutations	-	Wild type without mutations	INSTI: Q148K; Q148R; E157Q; NNRTI: G140S; L74M/I/F; T97A	184V; K103N	Wild type without mutations
New resistance mutations	No	INSTI: E138K, Q148R, L74LM and NNRTI: K103N, Y188L	No	INSTI: L100I; K103N	No	INSTI: Y143YS; Q148R
Oral ART after VF	DTG/3TC	DRVc/FTC/TAF	BIC/FTC/TAF	DRVc/FTC/TAF	DRVc/FTC/TAF	DRVc/FTC/TAF
VL supression	Yes	No	Yes	Yes	Yes	Yes

Table 2: Characteristics of patients with virologic failure. *Screening failure. Previous VF with probable RAMs against INSTI unnoticed. **Screening failure: 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

The RELATIVITY cohort lines up with the results provided by randomized clinical trials and other real-life cohorts (ATHENA, OPERA, CARLOS) in terms of effectiveness, tolerability, durability, and incidence of virological failures. Longer follow up is required to improve our knowledge regarding CBG/RPV

RELATIVITY