P096

Results at month 7 of CABO-CHANCE study: real-world-evidence (RWE) on the use of intramuscular cabotegravir plus rilpivirine long-acting (CAB+RPV LA) dosed every two months in virally suppressed people with HIV (PWH).

Carmen Hidalgo-Tenorio [1], M Ángeles Aguilera[2], Ignacio De Los Santos [2], Antonio Rivero[3], Ana Lopez Lirola [4], Teresa Lopez [5], Andrés Ruiz[6], Alberto Romero [7], Enrique Bernal [8], Patricia Sorni [9], Santiago Moreno [10], Mohamed Omar [11], Isabel Sanjoaquin [12], Onofre Martinez [13], Coral Garcia [1]

1-Hospital Universitario Virgen de las Nieves, Granada; 2-Hospital Universitario de La Princesa, Madrid; 3-Hospital Universitario Reina Sofia, Córdoba; 4-Hospital Universitario de Canarias, San Cristóbal de La Laguna;5-Hospital Santa Ana, Motril; 6-Hospital Universitario San Cecilio, Granada; 7-Hospital Universitario de Puerto Real; 8-Hospital Universitario Reina Sofia , Murcia; 9-Hospital Son Llàtzer, Mallorca; 10-Hospital Ramón y Cajal, Madrid; 11-Complejo Hospitalario de Jaén; 12-Hospital Lozano Blesa, Zaragoza; 13-Hospital General Universitario Santa Lucía, Cartagena, Spain.

Background: PWH have experienced a large increase in survival due to antiretroviral treatment (ART). There is currently a double paradigm shift in ART, from triple therapy to dual therapy (DT), and from oral to injectable DT with CAB+RPV LA. The aim of this study was to describe the PWH receiving CAB+RPV LA in Spain, its effectiveness, safety and the changes it may cause in inflammatory markers, HRQoL and sleep quality, health satisfaction and stigma at month 7.

Methods: Prospective (inclusion period June 2023-January 2024), longitudinal, Spanish multicenter (13 hospitals) study, including pre-treated PWH with HIV-1 RNA (VL) <50 c/mL at least 6 months that switching from any oral-ART to CAB+RPV LA. At baseline (BL) and 7 months (7M) thereafter CD4, CD8, VL, anthropometric parameters, creatinine clearance, lipids level, and inflammatory markers were assessed. And patient reported outcomes (PROs) using as instruments were WHOQOL-HIV-BREF, HIV Stigma Scale in Spaniards (HSSS), Pittsburgh sleep quality Index (PSQI) and also health satisfaction and adverse effects questionnaires. In a descriptive analysis, means with standard deviation were calculated for quantitative variables with a normal distribution (Kolmogorov–Smirnov test) and medians with interquartile range (IQR) for those with a non-normal distribution. Qualitative variables were expressed as absolute frequencies (%). In bivariate analyses, the chi-square test was used to compare qualitative variables. ClinicalTrials.gov ID: NCT06518408

Results: 224 PWH were included in this analysis (Table 1). Of the 149 participants, none met protocol-defined virologic failure criteria, 3.6% had HIV RNA levels ≥50 copies/mL, all were confirmed as blips (min: 52-max:176 copies/mL). There were no discontinuations for a mean follow-up of 87 patients/year. Between BL and 7M, there was statistically significant increase in BMI (25.7±3.6 kg/m^2 vs 25.8±4.1 kg/m^2; p=0.009), improvement in creatinine clearance (Cockcroft-Gault) [90.9 mL/min (IQR:78.2-101.6) vs 99.1 mL/min (IQR: 85.1-110.3); p=0.0001], and reduction in interleukin-6 levels [2.62 pg/mL(IQR: 1.4-6.1) vs 1.76 pg/mL(IQR: 1.4-3.1); p=0.002]. There were no changes in CD4/CD8 ratio, lipids, reactive C-protein, Fibrinogen or D-dimer. Participants reported statistically significant improvements in adverse events [reducing pain intensity 3 (IQR:3-3)vs 2(IQR:2-2); p=0.0001, and dysthermic sensation (35 vs 0.7%; p=0.0001)]. The results of Patient-Reported Outcomes was included in table2.

Table 1. Baseline **socio-demographic, clinic and antiretroviral treatment characteristics of PWH**	N= 224
Age (year), mean (± SD)	45.4 (±11.2)
Male at birth, n (%)	202 (90.2)
Time from HIV diagnosis (year), median (IQR)	12 (7-17)
CD4 Nadir, cells/uL, mean (± SD)	357.7±225.5
Baseline VL < 50 copies/mL, n (%)	215 (97.7)*
Virological failure, n (%)	0
Zenit viral Load HIV, log10, mean (± SD)	5.1(6.8)
Baseline CD4, (Cel/uL), mean (± SD)	792.1 (±320.6)
Baseline CD4/CD8 ratio, mean (± SD)	1.5(±5.96)
History of AIDS (A3, B3, C), n (%)	64 (28.6)
Time (years) that GRT** had been performed, median (IQR)	11.5 (6-15.2)
Previous GRT available, n(%)	0
Who propose the ART switch, n (%)	
Physician	187 (83.5)
HBV co-infection, n (%) ***	2 (0.9)
Risk factor for HIV transmission, n(%)	
- Heterosexual	33 (14.8)
- MSM	175 (78.5)
- Ex-IVDU	11 (4.9)
- other	4 (1.6)
Previous lines of ART, median (IQR)	4 (2-5)
Time on ART (years), median (IQR)	9.9 (5.9-15.5)
The baseline ART regimen, n (%)	
- 3DR	64 (28.6)
- 2DR	159 (71)
- 1DR	1 (0.4)
Oral lead with cabotegravir 30mg and rilpivirine 25mg, n (%)	0

Table 2. Patient reported outcomes results	At baseline N =224	At 7 month N =149	P**
Quality of life, n (%)			
Very bad	1 (0.5)	1 (0.7)	0.661
Regular	10 (4.6)	9 (6.4)	
Fair	75 (34.4)	30 (21.3)	
Fairly good	81 (37.2)	69 (48.9)	
Very good	51 (23.4)	32 (22.7)	
Health satisfaction, n (%)			
None	1 (0.5)	1 (0.7)	0.021
Little	17 (7.8)	1 (0.7)	
Some	41 (18.8)	18 (12.8)	
Quite a lot	118 (54.1)	91 (64.5)	
A lot	41 (18.8)	30 (21.3)	
Sleep quality, n (%)			
Quite Good	53 (24.3)	43 (30.5)	0.006
Good	96 (44)	67 (47.5)	
Quite bad	57 (26.1)	24 (17)	
Bad	12 (5.5)	7 (5)	
Stigma*, n (%)			
strongly disagree	28 (12.8)	25 (17.7)	0.81
disagree	44 (20.2)	28 (19.9)	
agree	43 (19.7)	27 (19.1)	
strongly agree	103 (47.2)	61 (43.3)	
*saying you have HIV is risky.			

** p>0.05 significance

*9 (2.3) PWH had > 50 cop/mL at baseline visit, they had blips.** Genotypic resistant test. GRT *** PWH were taking entecavir for HBV

Conclusions: This RWE study of CAB+RPV LA in PWH with extensive prior oral-ART and more than a decade since diagnosis, demonstrated that in the first 7 months of follow-up the LA regimen maintains viral suppression, with adverse effects decreasing (intensity Injection site pain and dysthermic sensation), improved creatinine clearance, decreased IL-6 and positive influences in health satisfaction and sleep quality. Funded with an unrestricted grant from ViiV Healthcare (ISS#222487)