19-21 GIUGNO ROMA
UNIVERSITA' CATTOLICA DEL SACRO CUORE CENTRO CONGRESSI EUROPA
RESEARCH and CARE: FROM BENCH, TO BEDSIDE, TO COMMUNITY
Promosso da SIMIT
16° CONGRESSO NAZIONALE ICAR
Italian Conference on AIDS and Antiviral Research
P 10
POSTER 4 YOU ICAR 2024

Unconventional use of Long-Acting CAB+RPV against HIV in PWH in need: real-world data at 48 weeks from an Italian bicentric cohort

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Introduction

- In this new "injectable era", there have been great expectations on the feasibility of injectable long-acting cabotegravir and rilpivirine (LA CAB-RPV) as a switch strategy in virosuppressed PWH. Concurrently, potential advantages from long-acting administration in comorbid and even in viremic PWH have been reported, showing benefit in reducing barriers to adherence and increasing viral suppression.We present our data from a cohort of PWH unable to maintain viral suppression due to adherence issues and with high rate of comorbidities who switched to LA CAB-RPV.

Methods

- We performed an observational study in two outpatient settings (Milan, Rome) from February 2021 to January 2024, enrolling PWH who switched to LA CAB-RPV, with and without viral suppression at BL (time of switch) and with high rate of comorbidities and worrisome clinical risks.We collected clinical features, comorbidities and viro-immunological parameters at BL,4W,12W,24W,48W.
- Kaplan-Meier (KM) was used to assess the probability of discontinuation.Cox regression analysis was used to evaluate potential predictors of discontinuation.

Results

- We enrolled 74 PWH, with at least 2 follow-up injection and a median of 7 injections (IQR 5–9).Ten of them received injections by the home care assistance service.
- Full population characteristics are summarized in Table 1.At BL 26 PWH (35.1%) reported poor adherence to oral daily ART (inability to maintain everyday pill-taking). Eleven PWH discontinued LA CAB-RPV (after a median of 3 injections) mainly for pain in injection-site (45.5%).
- Of 53 (72%) PWH who had virologic suppression before switch (VL <= 30 cps/ml, median TCD4 cell count, 681 cells/mm3, IQR 486-116) and with a median of 7 injections (IQR 5-9), 37 reached 48 W of follow up maintaining viral suppression.We registered only one virological failure at 12 W (4th injection):genotypic resistance testing was performed and showed N115H and H51Y mutations in the integrase gene and LA CAB-RPV was discontinued toward TAF/FTC/DRV/c. Twenty-one PWH (28.4%) started injections with unsuppressed viral loads (median TCD4 cell count of 594 cells/mm3, IQR, 339-1035; median VL 66 cps/ml, IQR, 40-215) with a median of 7 injections (IQR 2-8.5) of whom 11 reached 48 W of follow-up and 10 achieved viral suppression. By KM at 48W after switching LA CAB-RPV, the overall probability of discontinuation was 14.9% (Figure 1).Younger age was associated with discontinuation (per 1 year increase, aHR 0.93 95%CI, 0.88-0.99, p=0.048) by Cox regression.No safety issues were recorded

Conclusion

- Our results confirm the potential advantages in using LA CAB-RPV in PWH with adherence issues and comorbidities. Implementation of health programs could help to reach out more comorbid PWH in need and will increase virological suppression rates even in this complex population. A larger sample size and a longer follow-up are needed to define the real target population of this promising long-acting injectable regimen.

Variables	N=74
Age, median, years, (IQR, range)	53.5 (44.7-61)
Gender n (%)	
Cis-gender man	59 (79.7)
Cis-gender woman	12 (16.2)
Transgender woman	3 (4.1)
Ethnicity, n (%)	
Caucasian	65 (87.8)
African	3 (4.1)
Latino-American	5 (6.8)
Risk Factor n (%)	
MSM	35 (47.3)
Heterosexual	28 (37.8)
PWID	9 (12.2)
Zenith HIV-RNA as log10 copies/mL, median (IQR)	5.22 (4.48-5.72)
Nadir CD4, cells/mm3, median (IQR)	234.5 (62.5-484.2)
Time since HIV diagnosis, years, median (IQR)	11.8 (6.6-18.2)
Time on ART, years, median (IQR)	11 (8-18)
Antiretroviral regimen before BL, n (%)	
- 2NRTI+INSTI	27 (36.5)
- 2NRTI+NNRTI	2 (2.7)
- 2NRTI+PI	3 (4.1)
- 2DR (3TC/DTG, RPV/DTG)	36 (48.6)
- Other 2DR	3 (4.1)
- Other ARV regimen	3 (4.1)
CDC Stage C, n (%)	27 (36.5)
HIV VL ≤ 30 copies/ml at BL, n (%)	53 (71.6)
HIV VL ≥ 30 copies/ml at BL, n (%)	21 (28.4)
TCD4+ cells/mm3, median (IQR) at BL	651 (431-1014)
BMI, Kg/m2, median (IQR)	25.4 (22.6-30.2)
BMI > 30 Kg/m2, n (%)	14 (19)
Oral lead in, n (%)	7 (9.5)
Comorbidities, n (%)	
Cardiovascular disease	23 (31.1)
Endocrinological disorders	27 (36.5)
Hepatology disease	27 (36.5)
Psychiatric disease	18 (24.3)
Neurological disease	12 (16.2)
Pulmonary disease	2 (2.7)
Oncological disease	5 (6.8)

Table 1. *Full population characteristics at baseline.*

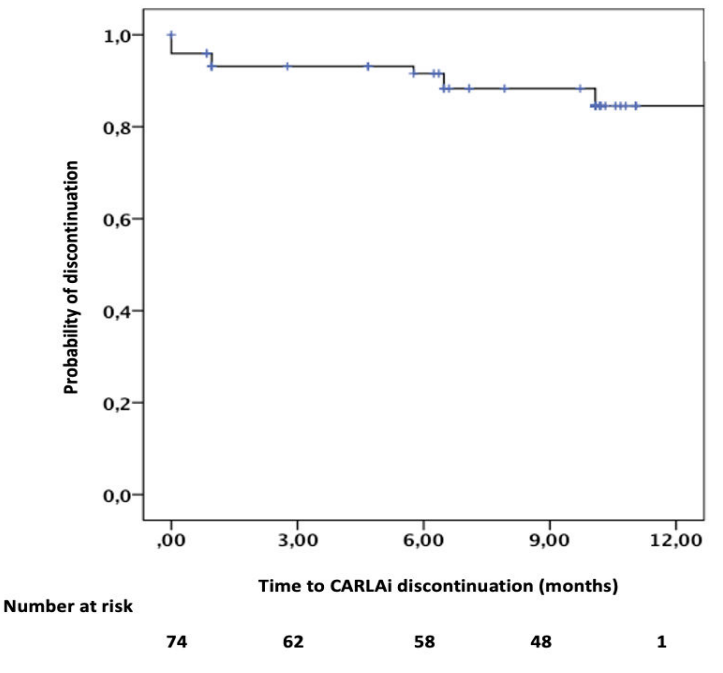

Figure 1: *Kaplan-Meier (KM) estimate at 12 months of the probability of treatment discontinuation after switching to LA CAB+RPV.*