16° CONGRESSO NAZIONALE ICAR Italian Conference on AIDS and Antiviral Research
19-21 GIUGNO ROMA
UNIVERSITA' CATTOLICA DEL SACRO CUORE
CENTRO CONGRESSI EUROPA

ORAL COMMUNICATION

HIV associated comorbidities: matters of the heart

OC 56 Metabolic and weight changes in people with HIV after switching to long-acting therapy with cabotegravir and rilpivirine: results from the SCohoLART study

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ABSTRACT

Background: Aim of the study was to evaluate metabolic and weight changes in people with HIV (PWH) and a long exposure to antiretroviral therapy (ART) switching to long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV).

Material and methods: SCohoLART (cohort study of HIV-positive people treated with long-acting antiretroviral therapy, NCT05663580) is a single-center, prospective, phase IV, cohort study designed to collect both samples and clinical data of PWH on virological suppression who switched to bimonthly LA CAB/RPV 600/900 mg, followed at the Infectious Diseases Department of IRCCS San Raffaele Scientific Hospital, Milan, Italy.

Participants' characteristics were reported as median (interquartile range, IQR) or frequency (%). Univariable mixed linear models were calculated to estimate crude mean changes in metabolic parameters and weight; slopes were reported with the corresponding 95% confidence intervals (95%CI). Participants starting or stopping statin during follow-up were excluded from the analysis.

Results: We evaluated 514 participants for a median follow-up of 13.1 (9.1-15.5) months. Overall, 467 (90.9%) PWH were male and median age was 48.9 (39.9-56.2). At the time of switching (baseline), median years from HIV diagnosis, of ART exposure and of virological suppression were 14.0 (8.8-20.5), 11.4 (7.9-17.4), and 8.6 (5.1-12.8), respectively. At baseline, median CD4+ count was 794 (602-994) cells/µL and median CD4+ nadir was 334 (214-512) cells/µL.

Regarding the metabolic profile, at baseline median weight was 76.0 (69.0-84.6) kg and median body mass index (BMI) 24.8 (22.8-27.0) kg/m2; total cholesterol (TC) was 180 (159-202) mg/dL, median high-density lipoprotein-cholesterol (HDL-c) 48.0 (40.8-57.0) mg/dL, and median low-density lipoprotein-cholesterol (LDL-c) 113 (96.0-136) mg/dL; moreover, TC/HDL-c ratio was 3.7 (3.1-4.4). Other participants' characteristics at baseline are reported in Table 1.

In participants switching to LA CAB/RPV, crude mean changes in weight and BMI were non statistically significant [+0.41 Kg/year (95%CI: -0.15, 0.97, p=0.15) and +0.14/year (95%CI: -0.04, 0.33, p=0.125), respectively], as well as mean increases in TC and LDL-c [0.45 (95%CI: -2.36, 3.26, p=0.754) and +0.48 (95%CI: -1.94, 2.9, p= 0.697), respectively] whereas crude mean changes in HDL-c and TC/HDL-c ratio were +2.97 mg/dL/year (95%CI: 1.88, 4.07, p=<0.0001) and -0.2/year (95%CI: -0.3, -0.11, p=<0.0001), respectively. Crude mean changes of other metabolic parameters are reported in Table 2.

Conclusions: In people switching to LA CAB/RPV treatment enrolled in the SCohoLART study, we observed a statistically significant increase in HDL-c and a concomitant reduction in the TC/HDL-c ratio, while no significant changes in weight and other metabolic parameters were described. Longer follow-up is needed to confirm these changes over time and assess the potentially favourable metabolic impact observed from the current data.

Table 1. Participants' characteristics at the start of long-acting cabotegravir-rilpivirine.

	N=514
Age (years), median (IQR)	48.9 (39.9-56.2)
Male, n (%)	467 (90.9)
HIV risk factor, n (%):	
Other	81 (15.8)
MSM	364 (70.8)
TD	11 (2.14)
Hetero	58 (11.3)
Years from HIV diagnosis, median (IQR)	14.0 (8.8-20.5)
Years of ART, median (IQR)	11.4 (7.9-17.4)
Years of virological suppression, median (IQR)	8.6 (5.1-12.8)
CD4+ count (cells/microL), median (IQR)	794 (602-994)
CD4+%, median (IQR)	34.9 (28.3-40.4)
Nadir CD4+ (cells/microL), median (IQR)	334 (214-512)
CD4+/CD8+, median (IQR)	1.0 (0.7-1.3)
Years of the ART regimen in use at LA start, median (IQR)	3.4 (2.2-5.4)
Number of ART drugs in ART regimen in use LA start, median (IQR)	3.0 (2.0-3.0)
Type of ART regimen in use at LA start, n (%):	
Other	5 (1.0)
2 NRTI + 1 PI	10 (2.0)
2 NRTI + 1 NNRTI	129 (25.1)
2 NRTI + 1 INSTI	189 (36.8)
2-drug regimen	177 (34.4)
PI-monotherapy	3 (0.6)
Not therapy	1 (0.2)
Weight (Kg), median (IQR)	76.0 (69.0-84.6)
Body Mass Index (kg/m^2), median (IQR)	24.8 (22.8-27.0)
Triglycerides (mg/dL), median (IQR)	99.0 (76.0-136)
Total Cholesterol (mg/dL), median (IQR)	180 (159-202)
Cholesterol HDL (mg/dL), median (IQR)	48.0 (40.8-57.0)
Cholesterol LDL (mg/dL), median (IQR)	113 (96.0-136)
Cholesterol total/HDL ratio, median (IQR)	3.7 (3.1-4.4)
Glucose (mg/dL), median (IQR)	89.0 (82.0-96.0)
HOMA-IR index, median (IQR)	1.7 (1.2-2.7)

Abbreviations: IQR, interquartile range; ART, antiretroviral therapy; LA, long-acting; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitors; NNRTI, non-nucleoside reverse transcriptase inhibitor; INSTI, integrase strand transfer inhibitor; HOMA-IR, homeostatic model assessment for insulin resistance.

Table 2. Crude mean changes in weight and other metabolic parameters.

Variable	Overall crude mean change (slope) per year (95% CI)
Weight (Kg)	0.41 (-0.15,0.97), p=0.15
Body Mass Index (kg/m^2)	0.14 (-0.04,0.33), p=0.125
Glucose (mg/dL)	0.17 (-2.1,2.44), p=0.884
HOMA-IR index	0.14 (-0.23,0.51), p=0.446
Triglycerides (mg/dL)*	-3.28 (-8.07,1.5), p=0.178
Total cholesterol (mg/dL)*	0.45 (-2.36,3.26), p=0.754
Cholesterol HDL (mg/dL)*	2.97 (1.88,4.07), p=<0.0001
Cholesterol LDL (mg/dL)*	0.48 (-1.94,2.9), p=0.697
Cholesterol total/HDL ratio*	-0.2 (-0.3,-0.11), p=<0.0001

*: Removed individuals starting or stopping statin during follow-up.

Abbreviations: CI, confidence interval; HOMA-IR, homeostatic model assessment for insulin resistance.