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 59
POSTER 4 YOU ICAR 2024

Neutral Metabolic Impact of Long-Acting CAB+RPV in PLWH: A Tuscan Multicenter Observational Study (LAHIV)

F. Lagi[1], G. Formica[2], E. Francalanci[2], M. Fognani[2], R. Paggi[2], G. Gasparro[2], M. Piccica[3], A. Pampaloni[4], D. Messeri[5], B. Rossetti[6], F. Panza[7], S. Costarelli[8], E. Riguccini[9], G. Sarteschi[10], M. De Gennaro[11], P. Corsi[11], M. Pozzi[1], G. Sterrantino[2], M. Tumbarello[7], P. Blanc[5], F. Bartalesi[3], D. Aquilini[4], C. Nencioni[6], S. Luchi[11], D. Tacconi[9], S. Sani[8], A. Vincenti[10], A. Bartoloni[1-2]

1) Azienda Ospedaliero-Universitaria Careggi, Università degli Studi di Firenze 2) Dipartimento di medicina sperimentale e clinica, Università degli studi di Firenze 3) Ospedale Santa Maria Annunziata, USL Toscana Centro 4) Azienda Ospedaliera Prato, USL Toscana Centro 5) Azienda Ospedaliera Pistoia, USL Toscana Centro 6) Azienda Ospedaliera Grosseto, USL Toscana Sud-Est 7) Azienda Ospedaliero-Universitaria Siena, Università degli Studi di Siena 8) Azienda Ospedaliera Livorno, USL Toscana Nord-Ovest 9) Azienda Ospedaliera Arezzo, USL Toscana Sud-Est 10) Nuovo Ospedale Apuane, USL Toscana Nord-Ovest 11) Azienda Ospedaliera Lucca, USL Toscana Nord-Oves

Introduction/Summary

- Since its introduction in Italy in June 2022, the cabotegravir (CAB) and rilpivirine (RPV) combination — a bimonthly intramuscularly administered regimen — represents the inaugural long-acting treatment to maintain virological suppression in HIV-1.
- This study evaluates shifts in creatinine, total cholesterol, CD4, and triglyceride levels from baseline to weeks 28 and 44 post-transition to this regimen.

Study Design

- We conducted a multicenter observational study across 10 of the 11 Infectious Disease units in Tuscany.
- We included all virologically suppressed (HIV-RNA <50 cp/mL) persons living with HIV (PLWH) older than 18 years who initiated CAB+RPV and who had creatinine, cholesterol, triglycerides, and CD4 measured at week 28 and week 44.
- PLWH missing any test or lacking sufficient follow-up were excluded.

Methods

- Descriptive analysis was employed to illustrate population characteristics.
- For the differences in values between baseline and 28 and 48 weeks, we used the Wilcoxon test for paired data

Results

DEMOGRAPHIC

- The study comprised 33 PLWH evaluated at week 28 and 13 PLWH at week 44
- Demographic clinical characteristics are reported in Table 1.
- In the 28-week group, nearly half reported dyslipidemia at baseline, but less than 30% were on statin treatment.
- In both groups, the most frequent pre-switch regimen included and integrase strand inhibitors

Table 1. Clinical/demographic characteristics of adults with HIV-1, switching to RPV+CAB, with laboratory tests available at the 28th and 44th week of follow-up in 10 out of 11 infectious disease units in Tuscany, Italy.

	PLWH with follow-up at 28 weeks (N=33)		PLWH with follow-up at 44 weeks (N=13)	
Italians, n (%)				
Gender, n (%)				
• Female	7	21.2	1	7.7
• Male	26	78.8	12	92.3
Age at entry, median [IQR]	51	42-57	47	41-53
Risk of HIV transmission, n (%)				
• Heterosexual	8	24.2	4	30.7
• MSM	15	45.4	6	46.1
• Intravenous drug users	5	15.1	3	23.1
• Other/ Not known	5	15.1	-	-
HIV-RNA Zenit, Log_{10} copies/mL, median [IQR]]	4.8	4.3-5.2	4.4	3.8-5.4
Nadir CD4 (cells/mL), median [IQR]	295	99-395	322	258-431
CD4+ T cells at baseline/µL, median [IQR]	860	692- 1040	956	640- 1085
CD4/CD8 cells at baseline, median [IQR]	1.1	0.9-1.3	1.1	0.8-1.5
Triglycerides at baseline mg/dL, median [IQR]	98	86-138	98	79-147
Cholesterol at baseline mg/dL, median [IQR]	187	153-213	178	144-188
Creatinine at baseline mg/dL, median [IQR]	0.93	0-81-1	0.88	0.81-1.01
Type of pre-switch regimen				
• NNRTI	11	33.3	8	61.5
• PI	5	15.1	3	23.3
• INSTI	25	75.5	7	53.8
BMI, median [IQR]	24.6	22.0-27.4	24.7	24.2- 29.4
Pre-switch regimen with TDF	2	6.1	3	23.1
Dyslipidemia	14	42.2	4	30.7
Statins therapy	9	27.3	4	30.7

ART: antiretroviral treatment; MSM: males who have sex with males; PI: Protease inhibitor; NNRTI: non-nucleoside reverse transcriptase inhibitors; INSTI: integrase strand transfer inhibitor

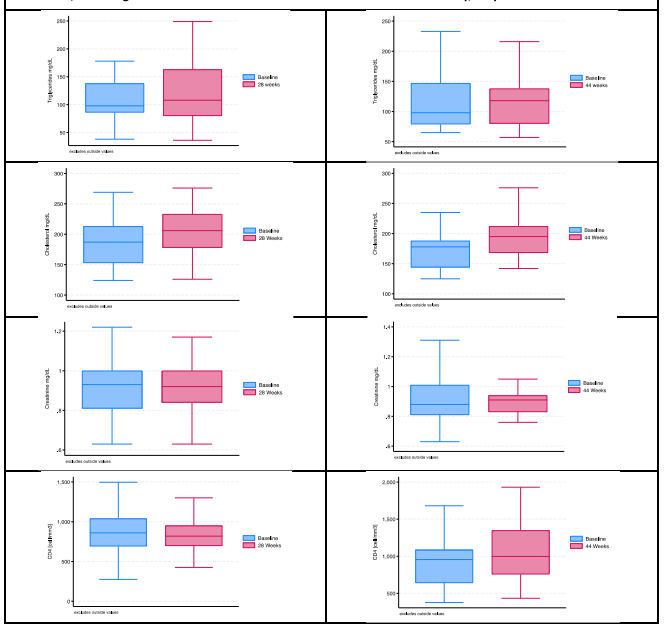
DiFFERENCES

- At 28 and 44 weeks, we observed no significant changes in triglycerides, cholesterol, creatinine, and CD4 count [Figure 1].
- A modest and not significative cholesterol increase was discernible post-switch, predominantly in PLWH not on statins (Figure 2).
- Although sample size constraints precluded comprehensive stratification, no marked biomarker fluctuations were noted even when stratifying by pre-switch regimen (PI, INSTI, and NNRTI).
- A median increase of 114 CD4 lymphocytes was observed at week 44, although not statistically significant, in PLWH already showing elevated CD4 lymphocyte levels

Conclusion

- Preliminary findings suggest the metabolic impact of transitioning to CAB+RPV is negligible.
- To confirm these findings and allow for more accurate stratification, further studies with extended follow-up and larger numbers of participants are required.

Figure 1. Differences in triglycerides, cholesterol, creatinine, and CD4 from baseline to weeks 28 and 44 in adults with HIV-1, switching to RPV+CAB in 10 out of 11 infectious disease units in Tuscany, Italy.



	PLWH with follow-up at 28 weeks (N=33)	p	PLWH with follow-up at 44 weeks (N=13)	p
Δ Triglycerides mg/dL, median [IQR]	0 [-22 24]	0.7955	5 [-58 20]	0.5067
Δ Cholesterol mg/dL, median [IQR]	10 [-4 32]	0.0606	17 [11 24]	0.1328
Δ Creatinine mg/dL, median [IQR]	-0.01 [-0.08 0.06]	0.6166	0.04 [-0.07. 0.05]	0.5760
Δ Cd4 , median [IQR]	31 [-45 120]	0.2312	114 [-31 266]	0.0747
Δ =difference from the baseline				

Figure 2. Differences in cholesterol and triglycerides at weeks 28 and 44 from baseline, by statin treatment status in adults with HIV-1, switching to RPV+CAB in 10 out of 11 infectious disease units in Tuscany, Italy.