Themed Discussion

People living with HIV: thinking of QoL

TD-1 EFFICACY, SAFETY AND METABOLIC CHANGES AT 6-MONTHS AFTER SWITCH TO LONG-ACTING INJECTABLE CAB/RPV: RESULTS FROM AN OBSERVATIONAL PROSPECTIVE MULTICENTER STUDY

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10.1136/sextrans-ICAR-2024.114

Abstract TD-1 Table 1 Clinical and demographic characteristics of the study population

Baseline characteristics	N	Missing data
Total PWH included	287	-
Mean age ± SD	48.0 ± 11.8	0
Sex (%)		0
Female	69 (24.0)	
Male	217 (75.6)	
Female transgender	1 (0.3)	
Caucasian ethnicity (%)	274 (95.4)	0
Risk factor for HIV acquisition (%)		0
Heterosexual	96 (33.4)	
IDU	24 (8.3)	
MSM	139 (48.4)	
Other	28 (9.7)	
HBsAg negative (%)	287 (100)	
HCV positive serology (%)	30 (10.6)	4
HIV-RNA > 30 copies/mL (%)	7 (2.4)	
Median CD4 cell/mm3 (IQR)	835.7 (599.0-1964.0)	0
CD4 >200 cell/mm³ (%)	284 (98.9)	
CDC stage (%)		3
A	175 (61.6)	
B	71 (25.0)	
C	38 (13.4)	
Mean BMI kg/m² ± SD	25.3 ± 4.2	44
Mean total-cholesterol mg/dL ± SD	187.4 ± 37.3	3
Mean HDL-cholesterol mg/dL ± SD	54.2 ± 15.9	3
Median triglycerides mg/dL (IQR)	92.0 (68.0-126.0)	3
Mean glycemia mg/dL ± SD	88.3 ± 19.8	1
Median creatinine mg/dL (IQR)	1.0 (0.8-1.1)	0
Mean eGFR ml/min ± SD	87.3 ± 23.6	0
Median ALT U/L (IQR)	23.0 (16.0-32.0)	5
Median AST U/L (IQR)	23.0 (18.0-28.0)	27
ART exposure in years (IQR)	10.3 (6.1-16.5)	0
Previous exposure ART regimen		0
PIs	258 (89.9)	
months (IQR)	0.0 (0.0-36.0)	
NNRTIs	243 (84.6)	
months (IQR)	24.0 (0.0-101.0)	
INSTIs	236 (82.2)	
months (IQR)	32.0 (0.0-66.5)	
Oral lead-in phase	108 (38.6)	7

SD: standard deviation; IQR: interquartile range; IDU: intravenous drug user; MSM: men who have sex with men; BMI: body mass index; eGRF: estimated glomerular filtration rate; ART: antiretroviral therapy; PIs: protease inhibitors; NNRTIs: non nucleoside reverse transcriptase inhibitors; INSTIs: integrase strand transfer inhibitors.

Abstract TD-1 Table 2 ART regimen before switch (3 missing data)

ART Regimen	N (%)
DTG/RPV	73 (25.7)
TAF/FTC/RPV	65 (22.9)
DTG/3TC	54 (19.0)
BIC/FTC/TAF	50 (17.6)
DTG/3TC/ABC	13 (4.6)
DOR/3TC/TDF	8 (2.8)
FTC/TAF/DRV/c	3 (1.1)
FTC/TAF/ELV/c	3 (1.1)
Others	15 (5.2)

DTG: dolutegravir; RPV: rilpivirine; TAF: tenofovir alafenamide; FTC: emtricitabine; BIC: bictegravir; ABC: abacavir; DOR: doravirine; DRV/c: darunavir/cobicistat; ELV/c: elvitegravir/cobicistat; RAL: raltegravir; ATV/c: atazanavir/cobicistat; ETV: etravirine; NPV: nevirapine; TDF: tenofovir disoproxil fumatate.

Background Injectable cabotegravir (CAB) and rilpivirine (RPV) long-acting (LA) is a new antiretroviral treatment (ART) for HIV-1 infection in virologically suppressed people with HIV (PWH). The study aims to describe outcomes at six months after switch to CAB/RPV and provide a specific subgroup analysis for PWH coming from tenofovir alafenamide (TAF)-containing regimens.

Material and Methods This was an observational prospective study from an Italian multi-center observational prospective database. PWH who started CAB/RPV LA injectable regimen from July 2022 to September 2023 were included. We assessed outcomes (efficacy, safety and metabolic variables including weight, renal, hepatic and blood-lipids changes) at six-months after switch, according to the previous regimen

Abstract TD-1 Table 3 Virological response at three subsequent follow-up evaluation

HIV-RNA (T0)	HIV-RNA (T1)	HIV-RNA (T2)	N (%)
Undetectable	Undetectable	Undetectable	141 (49.1)
Undetectable	Undetectable	NA	132 (45.9)
Detectable	Undetectable	NA	5 (1.7)
Undetectable	Detectable	NA	4 (1.4)
Undetectable	NA	NA	2 (0.7)
Detectable	Undetectable	Undetectable	1 (0.3)
Undetectable	Detectable	Undetectable	1 (0.3)
Undetectable	Undetectable	Detectable	1 (0.3)

T0, T1, T2 represent three different HIV-RNA dectection spermormed at unfixed but consecutive time points; NA: not available;

Abstract TD-1 Table 4 Metabolic-variables changes at 6 months after switch using the paired T-test

Change from baseline of metabolic-variables (T1-T0)	Mean	95% confidence interval	p-value	Total PWH	Missing data
Mean total-cholesterol mg/dL	1.08	-2.1 to 4.3	0.50	277	10
Mean HDL-cholesterol mg/dl	0.21	-1.4 to 1.9	0.80	278	9
Mean LDL-cholesterol mg/dl	0.83	-2.3 to 4.0	0.60	274	13
Mean triglycerides mg/dl	2.73	-3.7to 9.2	0.40	278	9
Mean BMI (kg/m²)	-0.25	-0.48 to -0.03	0.0283	250	37
Mean weight (kg)	-0.57	-1.14 to 0.00	0.0527	273	14
Mean glycemia in non-diabetics PWH (mg/dL)	0.11	-1.2 to 1.5	0.86	269	9
Mean glycemia in diabetics PWH (mg/dL)	35.55	-17.5 to 88.6	0.16	9	0
Mean creatinine (mg/dL)	-0.06	-0.1 to -0.0	<.0001	280	7
Mean eGFR (ml/min)	6.29	3.9 to 8.7	<.0001	281	6

T0: baseline (at switch to CAB/RPV); T1: at 6 months after switch; NA: not applicable.

Abstract TD-1 Table 5 Metabolic-variables changes at 6 months after switch, comparing (N=161) and TAF- containing (N=126) previous regimens using the T-test (3 missing dot)

Change from baseline of metabolic-variables (T1-T0)	Mean	95% confidence interval	p-value	Total PWH	Missing data
Mean total-cholesterol mg/dL					
Non TAF-containing previous regimens	0.07	-4.4 to 4.5	0.51	151	10
TAF-containing previous regimens	2.23	-2.4to 6.9		123	3
Mean HDL-cholesterol mg/dl					
Non TAF-containing previous regimens	-0.26	-2.7 to 2.1	0.56	152	9
TAF-containing previous regimens	0.71	-1.6 to 3.0		123	3
Mean LDL-cholesterol mg/dl					
Non TAF-containing previous regimens	-0.74	-5.2 to 3.7	0.29	148	13
TAF-containing previous regimens	2.69	-1.9 to 7.3		123	3
Mean triglycerides mg/dl					
Non TAF-containing previous regimens	9.83	-0.4 to 20.1	0.01	152	9
TAF-containing previous regimens	-5.81	-13.0 to 1.3		123	3
Mean BMI (kg/m²)					
Non TAF-containing previous regimens	-0.15	-0.42 to 0.11	0.28	130	31
TAF-containing previous regimens	-0.40	-0.77 to -0.03		118	8
Mean weight (kg)					
Non TAF-containing previous regimens	-0.27	-0.99 to 0.43	0.22	147	14
TAF-containing previous regimens	-0.99	-2.0 to -0.0		123	3
Mean glycemia in non-diabetics PWH (mg/dL)					
Non TAF-containing previous regimens	0.62	-1.1 to 2.4	0.40	147	NA
TAF-containing previous regimens	-0.54	-2.7 to 1.6		119	NA
Mean glycemia in diabetics PWH (mg/dL)					
Non TAF-containing previous regimens	20.60	-82.9 to 124.1	0.50	5	NA
TAF-containing previous regimens	54.25	-27.2 to 135.7		4	NA
Mean creatinine (mg/dL)					
Non TAF-containing previous regimens	-0.07	-0.1 to -0.0	0.22	153	8
TAF-containing previous regimens	-0.05	-0.1 to -0.0		125	1
Mean eGFR (ml/min)					
Non TAF-containing previous regimens	6.27	2.8 to 10.4	0.75	153	8
TAF-containing previous regimens	5.93	3.3 to 8.5		125	1

T0: baseline (at switch to CAB/RPV); T1: at 6 months after switch NA: not applicable; TAF: tenofovir alafenamide;

(TAF-based or not). Then an analysis of metabolic-variables changes in the group of PWH coming from TAF-containing regimens was performed, compared with all other groups. Statistical analysis was performed using the paired Student's t-test to evaluate changes from baseline to six-months follow-up; the analysis of variance was used to compare changes between different ART regimens. P<0.05 was considered statistically significant.

Results 287 PWH were included, clinical and demographic variables at baseline are reported in table 1, and previous ART regimens, in 126/287 (43.9%) TAF-based, in table 2. Virological outcomes were presented in table 3. After six months, we observed 273 (95%) cases of sustained viral suppression and 23 (8.0%) cases of treatment interruption. Metabolic-variables changes at 6-months were reported in tble 4. We observed a borderline statistically significant reduction in mean body weight of -0.57 kg (SD ± 4.84; [95% CI, 1.14 to .00]; p=0.0527), mean BMI of -0.25 kg/m2 (SD ± 1.80; [95% CI, -0.48 to -.03]; p=0.0283) and mean creatinine of -0.06 mg/dL (SD ± 0.12; [95% CI, -.01 to -.00]; p<.0001) with a statistically significant increase of estimated glomerular filtration rate (eGFR) of 6.29 ml/min (SD ± 20.20; [95% CI, 3.9 to 8.7]; p<.0001). Variance analysis showed no statistically significant results for metabolic-variables changes when comparing INSTIs-containing vs non INSTIs-containing previous regimens and NNRTIs-containing vs non NNRTIs-containing previous regimens. Finally, comparing TAF-containing vs non-TAF containing previous regimens (table 5), no difference emerged, besides a decline of tryglicerides in PWH coming from TAF-cointaining regimens compared to those coming from non-TAF containing regimens (-5.8 vs +9.8 mg/dL, p=0.02).

Conclusions Our real-life data show a favorable outcome of CAB/RPV LAinjectable regimen at six months after switch in terms of efficacy, safety and metabolic-variables changes, with an improvement in renal function and reduction in body weight and BMI. Moreover, interrupting a TAF-based regimen does not appear to be associated with significant changes in metabolic variables, except for a triglyceride reduction.

People living with HIV: thinking of QoL

TD-2 PATIENT-REPORTED OUTCOMES (PROS) IN PEOPLE LIVING WITH HIV TREATED WITH LONG-ACTING INJECTABLE ANTIRETROVIRAL THERAPY (LAI-ART)

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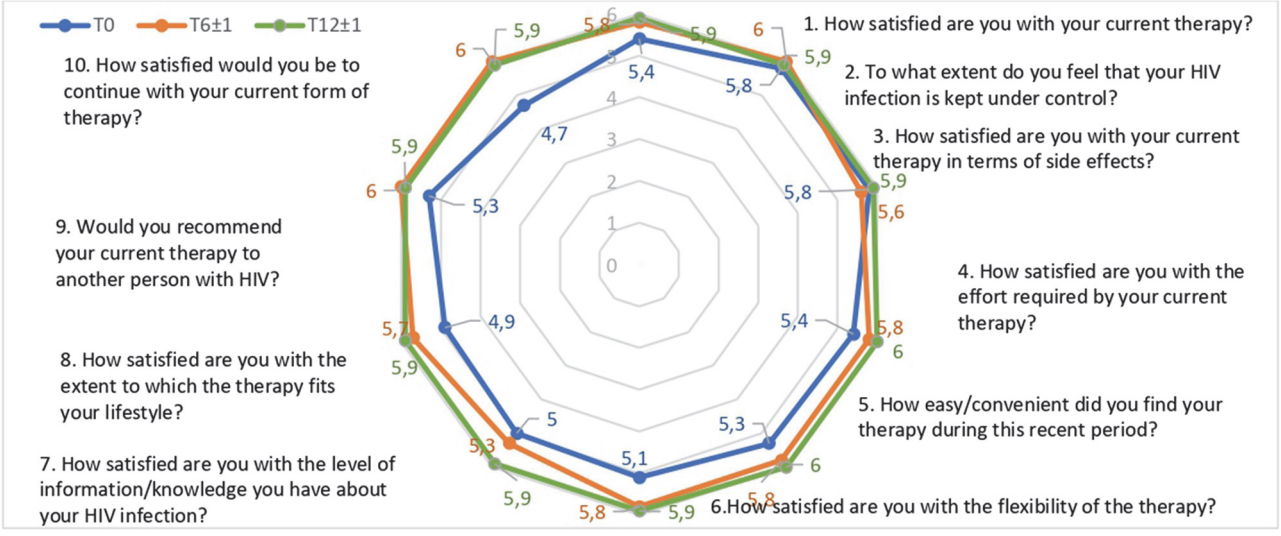
10.1136/sextrans-ICAR-2024.115

Background The introduction of LAI-ART could affect the life of PLWH and patient-reported outcomes (PROs) could be a fundamental instrument to explore this aspect. This study aims to evaluate the satisfaction with LAI-ART in a cohort of PLWH.

Methods This is a monocentric prospective study. We enrolled PLWH who switched to Cabotegravir (CAB) and Rilpivirine (RPV) bimonthly LAI-ART at the Clinic of the Infectious and Tropical Diseases Clinic of the ASST Spedali Civili of Brescia from March 2023. PROs were evaluated through three questionnaires: Quality of Life and Health Status Scale (EQ-5D), Antiretroviral Therapy Satisfaction Scale (HIV-TSQs), and Resilience Scale (RS). These questionnaires were administered to all the subjects before the beginning of LAI-ART (T0) and after 6 (T1) and 12 months (T2).

Results We included 51 individuals: 42 (82.35%) men, 48 (94.12%) Italian, with a mean age of 45.25 years (SD 11.2); 25 subjects completed T1 (one discontinued LAI ART due to worsening of depressive symptoms) and 10 completed T2 (one discontinued due to injection site reaction).

At T0, EQ-5D scores were very high (mean scoring between 1.0 and 1.28 for all the items) with a mean perception of health status of 82.28 out of 100. HIVTSQs questionnaire showed the lowest scores in the items related to the



Abstract TD-2 Figure 1 Antiretroviral therapy satisfaction scale (HIV-TSQs) at T0 (baseline), T1 (6 months follow up), at T12 (12 months follow up)