(nAbs) against XBB.1.16 and JN.1, were measured at baseline (BL) and at 1, 4, 6, 9, and 12 months, while T-cell responses to Spike and nucleocapsid peptides at BL, 1, 4 and 12 months. The primary outcome was the magnitude and durability of immune responses between groups over time. Groups were compared using t-test or Mann–Whitney U test for continuous variables and Fisher's exact test for categorical variables. Immune responses over time are shown as boxplots.

Results Sixty-four patients were included (mean age 67±12 years; 47% male). BL characteristics were comparable between groups, except for prior vaccine doses (p=0.018) (table 1). At BL, anti-S IgG, anti-N IgG, nAbs, and Spike- and nucleocapsid-specific T-cell responses were similar between arms. At randomisation, only the median value of anti-N IgG showed differences between arm 1 vs arm 2 (2.48 vs 1.55 log2S/CO; p=0.04). At month 6 (2 months post-vaccination), anti-S and anti-N IgG were significantly higher in the vaccinated versus not (13.44 vs 12.03 log2BAU/mL; p<0.001 and 2.33 vs 1.20 log2S/CO; p=0.02). NAbs titers were statistically higher for JN.1 in arm 1 (5.32 vs 4.32 log2reciprocal serum dilution; p=0.023), while similar for XBB.1.16 (6.32 vs 5.32 log2reciprocal serum dilution; p=0.66). By month 9, differences attenuated: anti-S IgG remained statistically higher in the vaccinated (12.02 vs 11.48 log2BAU/mL; p=0.034), with a trend for anti-N IgG (1.23 vs -0.29 log2S/CO; p=0.08) and comparable nAb titers levels. By 12 months, anti-Spike IgG median levels were fully comparable between groups (11.60 vs 11.59 log2BAU/mL; p=0.4). nAbs titers were similarly distributed for JN.1 (3.32 vs 3.32 log2reciprocal serum dilution; p>0.9) and XBB.1.16 (4.32 vs 4.82 log2reciprocal serum dilution; p>0.9). Spike- and nucleocapsid-specific T-cell responses were comparable, revealing a measurable response in both arms over time (figure 1).

Conclusions In mAb-treated patients with mild-to-moderate SARS-CoV-2 infection, vaccination after 4 months elicited a transient rise in anti-S IgG and neutralising activity, but this advantage progressively waned, and by 12 months, immune response was comparable between vaccinated and unvaccinated participants. These findings suggest a limited benefit of early vaccination in this setting.

Clinical insights of long-acting treatment

SC19 WEIGHT AND LIPID CHANGES AFTER SWITCHING TO LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE

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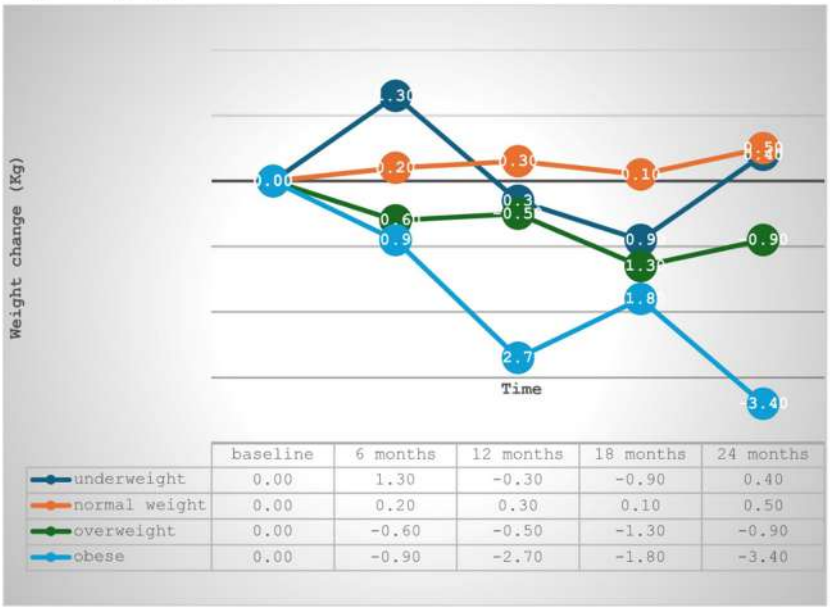
Background The long-acting (LA) treatment with cabotegravir (CAB) and rilpivirine (RPV) has been reported to have a neutral

Abstract SC19 Table 1 Metabolic Parameters at Baseline and During Follow-Up After Switch to LA CAB+RPV

Level of blood glucose, total cholesterol (TC), HDL cholesterol (HDL), LDL cholesterol (LDL) and triglycerides at baseline (T0), one (T1) and two (T2) years after initiating long acting cabotegravir and rilpivirine (median, interquartile range).

Variable mg/dL	T0	T1	P value T1-T0	T2	P value T2-T0
Blood glucose	87 (80-93)	86 (79-94)	0.76	88 (81-94)	0.076
TC	186 (161-208)	193(170-214)	0.0011	191 (168-211)	0.030
HDL	50 (42-60)	52 (44-61)	0.32	53 (45-62)	0.011
LDL	112 (90-130)	114 (97-135)	0.16	114 (92-134)	0.30
Triglycerides	95 (72-133)	100 (75-145)	0.0009	100 (75-133)	0.32

Baseline weight change was set to zero for all groups. Values next to each data point indicate mean weight change (kg).



	baseline	6 months	12 months	18 months	24 months
underweight	0.00	1.30	-0.30	-0.90	0.40
normal weight	0.00	0.20	0.30	0.10	0.50
overweight	0.00	-0.60	-0.50	-1.30	-0.90
obese	0.00	-0.90	-2.70	-1.80	-3.40

Abstract SC19 Figure 1 Mean weight change over time by BMI category

effect on weight and blood lipids in people with HIV (PWH) during treatment. However, few real-world data are available from observational cohorts.

Materials and Methods This was a multicentre prospective observational study conducted within the SCOLTA (Surveillance Cohort Long-Term Toxicity Antiretrovirals) project. PWH RNA<50 copies/mL switched to CAB+RPV LA from 2022 onwards with at least one year of follow-up were included. Variables were compared using the paired t-test (1- and 2-years vs baseline). To determine the association between change from baseline and PWH's characteristics, we run a multivariate model including age, sex, BMI, CD4-T cells and the baseline value of the variable.

Results A total of 671 PWH were enrolled, with a median follow-up period of 22 months (interquartile range, IQR: 13–29 months). The median age of the participants was 49 years (IQR 40–58) and median duration of ART was 10.3 years (IQR 6.4–16.7). The median body mass index (BMI) at enrolment was 24.6 kg/m^2 (IQR 22.6–27.0).

During the follow-up, mean weight did not change significantly in the study population, with a change of -0.25 kg (95% CI: -0.59 to +0.08, p = 0.1403) after one year and -0.18 kg (95% CI: -0.70 to +0.33, p = 0.4864) after two years. The multivariable analysis revealed that the probability of weight change was significantly associated with baseline BMI, with obese people experiencing a reduction in weight, significantly greater compared to normal-weight (mean estimate -2.79 kg, SE 0.64, p<0.0001), and those who were overweight showed a tendency towards significant reduction (mean estimate -0.75 kg, SE 0.38, p=0.052; see figure 1). Age, sex and CD4 count did not correlate with the probability of weight change.

Regarding blood lipids, LDL levels remained stable during the study, while total cholesterol increased significantly, driven by an increase in HDL levels (table 1).

Multivariable analysis revealed that trends in total cholesterol, HDL and LDL cholesterol were inversely correlated with their baseline values (mean estimated change: -0.36 ± SE 0.04, p <.0001; -0.39 ± SE 0.05, p <0.0001; and -0.38 ± SE 0.04, p <0.0001, respectively). HDL changes also showed a direct linear correlation with female sex (estimate: +4.02 ± SE 1.60, p = 0.0123) and age (estimate: +0.12 ± SE 0.05, p = 0.0322).

Conclusions Body weight remained stable in SCOLTA after switching to LA CAB+RPV during two-years of observation. People with higher BMI at baseline were more likely to lose weight during treatment, confirming the feasibility of this regimen also in obese people and reassuring towards the concern of further weight gain and the consequent difficulty of achieving the proper injection depth. The modest but significant increase in cholesterol levels was driven by an increase in HDL, confirming the metabolic safety of the LA regimen.

SC20 USE OF NEXT-GENERATION SEQUENCING (NGS) AS AN ADDITIONAL TOOL TO EVALUATE SUITABILITY OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE TREATMENT AND TAILORING FOLLOW-UP

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Background Long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) is an effective and well-tolerated antiretroviral switch option for virologically suppressed people with HIV (PWH). However, incomplete treatment history or unavailable historical Genotype Resistance Testing (hGRT) may limit access to LA therapy. We implemented Next-Generation Sequencing (NGS) on proviral DNA as an additional tool to refine eligibility, stratify virological failure (VF) risk, and tailor HIV-RNA monitoring frequency beyond current guideline recommendations.