Abstract SC22 Table 1–3

Table 1 - **LA CAB+RPV discontinuation rates**

CATEGORY	PWH (N)	RATE (%)
AES	44	47.3
PATIENT'S DECISION	15	16.1
LOST TO FOLLOW-UP	11	11.8
VF	10	10.8
OTHER (*)	6	6.5
DECEASED	4	4.3
PREGNANCY	3	3.2

(*) 3 were hospital relocations, 3 were considered at risk for VF

Abbreviations: PWH, people with HIV; LA, long-acting; CAB, cabotegravir; RPV, rilpivirine; AEs, adverse events; VF, virologic failure.

Table 2 – **AEs classification**

CATEGORY	PWH (N)	RATE (%)
ISRS	20	45.5
ARTHROMYALGIAS	5	11.4
INFECTIOUS COMPLICATIONS (*)	5	11.4
DERMATOLOGIC	3	6.8
CNS	2	4.5
GI	2	4.5
OTHER	4	9.1

(*) 2/5 were specified as HBV infection reactivation; the remaining 3 infectious complications were not further defined.

Abbreviations: PWH, people with HIV; AEs, adverse events; ISRs, injection site reactions; CNS, central nervous system; GI, gastrointestinal; HBV, Hepatitis B Virus.

Table 3 – **oral regimen after LA CAB/RPV discontinuation**

CATEGORY	REGIME POST - LA	PWH (N)	RATE (%)
OTHER	INSTI-based	3	4.0
AES	INSTI+NNRTI-based	8	10.7
AES	INSTI-based	26	34.7
AES	NNRTI-based	9	12.0
AES	PI-based (*)	1	1.3
VF	INSTI-based	5	6.7
VF	PI-based (*)	5	6.7
PREGNANCY	INSTI-based	3	4.0
SUBJECT'S DECISION	INSTI+NNRTI-based	6	8.0
SUBJECT'S DECISION	INSTI-based	6	8.0
SUBJECT'S DECISION	NNRTI-based	3	4.0

(*) One study participant who developed AEs and one who developed VF were already on PI treatment before LA CAB/RPV; the remaining 4 individuals who had to induce a PI-based regimen all underwent VF under LA CAB/RPV.

Abbreviations: LA, long acting; CAB, cabotegravir; RPV, rilpivirine; AEs, adverse events; VF, virologic failure; INSTI, Integrase Strand Transfer Inhibitor; NNRTI, Non-Nucleoside Reverse Transcriptase Inhibitor; PI, Protease Inhibitor.

The resumption of the same drug co-formulation utilized before the LA regimen occurred in 20.0% (2/10), 76.9% (15/65), and 84.1% (37/44) of PWH who interrupted LA due to VF, due to any cause other than VF, and due to AEs, respectively. Overall, 92.1% of regimens after LA interruption were NNRTI (16%), INSTI (57.3%), or NNRTI+INSTI (18.7%)-based. No new AEs were recorded after switching back to oral therapy throughout the whole cohort. Six months after resuming oral therapy, HIV-RNA loads <30 copies/mL and <200 copies/mL were recorded in 96.0% (72/75) and 98.7% (74/75) of individuals, respectively.

Conclusions Among individuals who interrupted injectables for reasons other than VF, the majority returned to the same pre-LA oral co-formulation. The superimposition of CAB+RPV pharmacokinetic tail with an oral NNRTI and/or INSTI-based regimen did not lead to the development of AEs, even in people with a previous AE to CAB or RPV. Six months after the reintroduction of oral therapy, the virologic suppression rate was high throughout the cohort.

SC23 SAFETY OF CABOTEGRAVIR + RILPIVIRINE LONG-ACTING REGIMEN AMONG PLWH WITH PREVIOUS HBV EXPOSURE: PRELIMINARY RESULTS OF THE SCRIBE STUDY

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Introduction Cabotegravir + rilpivirine long-acting regimen (CARLA) has no anti-HBV activity and is not recommended for PLWH with active HBV co-infection. No data exist on its hepatic safety among PLWH with resolved HepB (rHepB), especially among those with isolated HBcAb+ (IsHBcAb+).

Materials and Methods Retrospective multicenter observational study including PLWH on CARLA. Primary aim was to demonstrate hepatic safety among PLWH with rHepB (HBsAg-, HBcAb+, HBsAb+/-), assessed by analysing FIB-4 and ALT trends. Temporal trends of FIB-4 and ALT were described using a mixed linear model with a random intercept and slope adjustment. The incidence rate of hepatitis flare (increase 3X the ALT normal values) was reported, and factors associated with hepatitis flare including Liver Steatosis assessed by HSI were described using standard survival analyses.

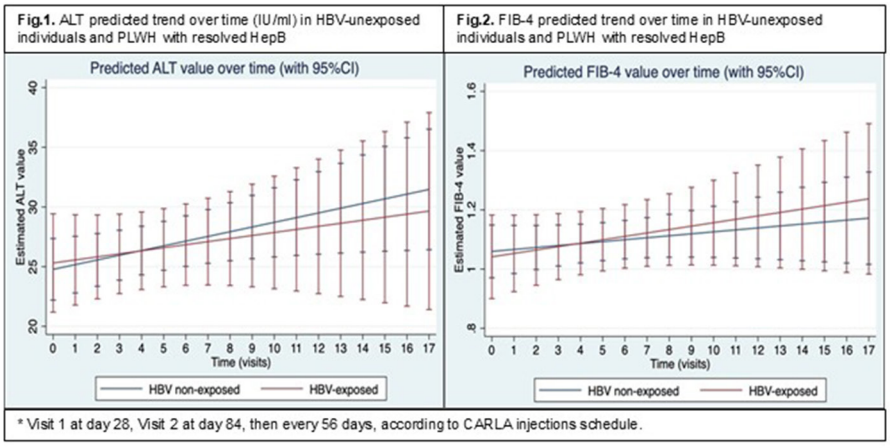
Results 394 PLWH were included from 4 centres, with a median follow-up of 1.98 years (IQR: 0.99-2.53). Their main features are shown in table 1. The mixed model did not find any trend for worse evolution of ALT and FIB-4 values in rHepB compared with non-exposure to HBV (coef. -0.14, 95%CI -0.84-0.56, p=0.697 and coef. 0.01, 95%CI -0.02-0.03, p=0.669, respectively), as shown in figure 1 and figure 2. HSI score was significantly associated with ALT increase (coef. 0.88, 95%CI 0.61-1.15, p<0.001).

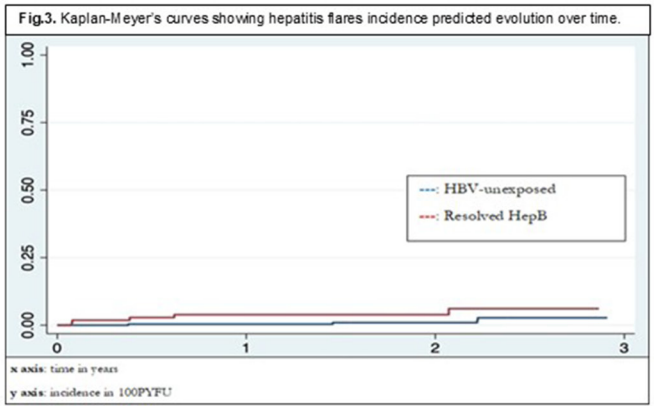
We observed 9/394 (2.3%) hepatitis flares: 4/283 (1.4%) among HBV-unexposed and 5/111 (4.5%) in PLWH with rHepB, 2/24 (8.3%) with IsHBcAb+: incidence was 0.8 and 2.7 per 100PYFU among PLWH HBV-unexposed and with rHepB, respectively (IRR 0.32, 95%CI 0.08-1.25, p=0.090). For people with IsHBcAb+, the incidence rate was slightly higher (6.0 per 100PYFU with IRR 0.18, 95%CI 0.04-1.30, p=0.080). Survival analyses did not find a role of rHepB in the risk of hepatitis flare, whereas a higher HSI score was slightly associated with hepatitis flare, even at the limit of statistical significance (aHR 1.11, 95%CI 1.00-1.23, p=0.061), as shown in figure 3.

In IsHBcAb+ PLWH there was a significantly higher risk of flare (aHR 11.15, 95%CI 1.67-74.28, p=0.013), and for this population, a higher HSI had an impact (aHR 1.14, 95%CI 1.02-1.27, p=0.018).

No confirmed cases of HBV reactivation were observed. One person with IsHBcAb+ had a flare associated with HBsAb seroconversion and HBV DNA 17 IU/ml, followed by spontaneous resolution.

Conclusions CARLA is safe, considering the FIB-4 and ALT trends among PLWH with rHepB. Hepatitis flares seemed to be related to Liver Steatosis. rHepB did not impact hepatitis flares risk, whereas IsHBcAb+ was associated with a higher risk of liver events, even though it was not related to HBV reactivation.





Abstract SC23 Figure 1–3

Abstract SC23 Table 1 Main features of study population

		Overall (N=394)	HBV unexposed (N=283)	Resolved Hepatitis B (N=111)
Gender: Males, n (%)		323 (82.0)	230 (86.3)	93 (83.8)
Age, years, median (IQR)		48 (40-57)	45 (38-54)	56 (49-61)
Italian born, n (%)		326 (82.7)	230 (81.3)	96 (86.5)
Type of risk exposure, n (%)	GBMSM	219 (55.6)	163 (57.6)	56 (50.5)
	MSW/WSM	121 (30.7)	96 (33.9)	25 (22.5)
	IVDU	39 (9.9)	11 (3.9)	28 (25.2)
	Other	15 (3.8)	13 (4.6)	2 (1.8)
BMI, median (IQR)		24.5 (22.6-27.2)	24.4 (22.5-26.8)	25.0 (22.8-27.9)
Length of infection, years, median (IQR)		11.5 (6.9-18.7)	10.6 (5.8-15.6)	17.8 (10.1-27.0)
CD4+ nadir, cell/mmc, median (IQR)		340 (141-514)	360 (157-515)	303 (140-454)
Liver steatosis (HSI>36), n (%)		121 (30.7)	89 (31.5)	32 (28.8)
Alcohol use: Abuse, n (%)		18 (4.6)	13 (4.6)	5 (4.5)
Number of previous therapeutic lines, median (IQR)		3 (2-5)	3 (2-5)	4 (3-6)
Isolated HBcAb+, n (%)		23 (5.8)	--	23 (20.7)
Previous HCV infection, n (%)		45 (11.4)	22 (7.8)	23 (20.7)
FIB-4, median (IQR)		0.90 (0.68-1.24)	0.82 (0.64-1.15)	1.08 (0.85-1.41)
ALT, IU/ml, median (IQR)		21 (16-30)	22 (16-32)	20 (15-27)
Follow up, years, median (IQR)		1.98 (0.99-2.53)	1.98 (0.99-2.53)	1.98 (1.15-2.38)
CARLA Discontinuation, n (%)		68 (17.3)	50 (17.7)	18 (16.2)
Virologic failures, n (%)		10 (2.5)	4 (1.4)	6 (5.4)
Hepatitis flares, n (%)		9 (2.3)	4 (1.4)	5 (4.5)

Legend: GBMSM: Gay, Bisex and other Men who have Sex with Men; MSW/WSM: Men who have Sex with Women/Women who have sex with Women; IVDU: Intravenous Drugs Users; BMI: Body Mass Index; IQR: Interquartile range.

These results will be updated soon with data coming from other 4 Italian centres.

SC24 IMPACT OF CABOTEGRAVIR/RILPIVIRINE ON PATIENT-REPORTED OUTCOMES: REAL-WORLD DATA FROM A MULTICENTER COHORT

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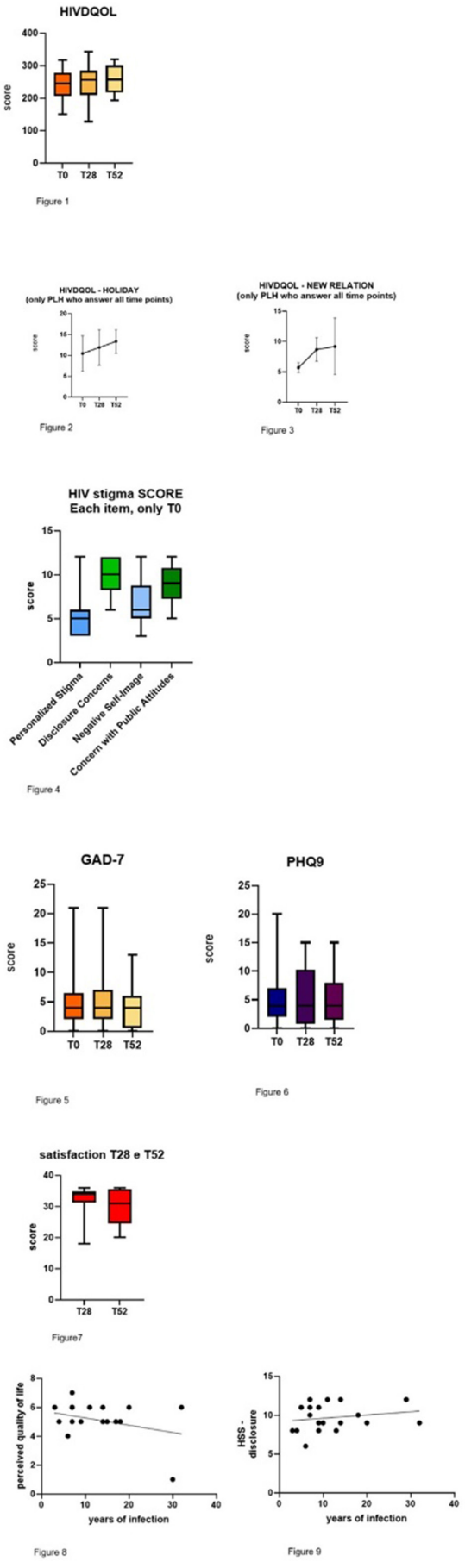
Background The efficacy and safety of cabotegravir/rilpivirine (CAB/RPV) has been demonstrated and initial results suggest that it is preferred by people living with HIV (PWH). It is not yet known how much it actually affects quality of life and whether there are social factors that can predict its failure.

Methods It is a prospective multicenter study (S.M. Goretti Hospital and Sant'Andrea University Hospital Infectious Diseases Clinics) where PROs (patient-reported outcomes) were collected before starting CAB/RPV and then every 6 months for up to two years (T0, T28 weeks, T52 w, T76 w, T100 w), via electronic forms.

Here we analyse some of them, until T52w: HIV Dependent Quality of Life (HIVDQoL), HIV Stigma Scale (HSS), HIV Treatment Satisfaction questionnaire status and change versions (HIVTSQs and HIVTSQc), PHQ-9(mental health assessment), GAD-7 (generalized anxiety disorder). The Spearman test was performed to assess correlations between continuous variables and longitudinal evaluations were conducted using the nonparametric Wilcoxon test and Friedman test.

Results 44 people were involved, including 13 women at birth (29%) and 1 black African person. Adherence was 74% at time



Abstract SC24 Figure 1–9