Use of Dual ART in individuals with different HBV serological patterns

HIV Clinical Topics, Barcelona, Friday 20th September 2024

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Conflict of Interest: JKR

- **Honoraria for lectures and/or consultancies from Abbvie, Berlin Cure, Boehringer, Galapagos, Gilead, Janssen, MSD, NPO Petrovax Pharm LLC, and ViiV.**

- **Research grants from Dt. Leberstiftung, DFG, DZIF, Gilead, Hectorstiftung, NEAT ID.**

Use of Dual ARV Therapy in individuals with different HBV serological patterns

- **Anti-HBs-negative**
- **Anti-HBc-negative**

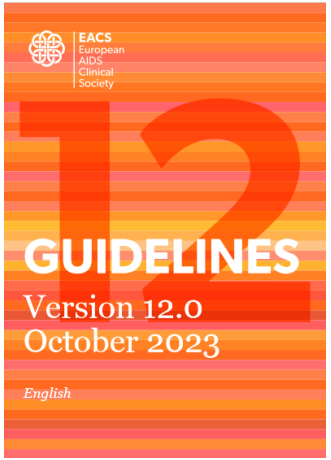
No past or chronic HBV infection
No or unsuccessful HBV vaccination

Do not forget to vaccinate against HBV

Hepatitis B Virus (HBV)	Shared risk with HIV of contracting infection. Untreated HIV accelerates progression of liver disease	Vaccinate if seronegative. Repeat doses until anti-HBs antibodies ≥ 10 IU/L / ≥ 100 IU/L according to national Guidelines. In order to reach ≥ 100 IU/L in non-responders repeat 3 doses if anti-HBs < 10 IU/L, 1 dose if anti-HBs < 100 IU;[II] consider double dose (40 µg) or use more immunogenic vaccines in particular with low CD4 count and high HIV VL. No benefit for intradermal application. See page 127

Vaccination, see page 99

12. Persons lacking anti-HAV IgG antibodies or anti-HBs antibodies should be offered vaccination for the respective virus to prevent infection regardless of their CD4 count. The response to the HBV vaccine is influenced by the CD4 count and level of HIV-VL. In persons with low CD4 count (< 200 cells/µL) and ongoing HIV replication, ART should be initiated first, prior to respective vaccination. The use of the more immunogenic vaccine Heplisav B should be evaluated where available. Heplisav B may be used for primary immunization to reach better responses. Because of the lack of randomized data on the impact of immunisation in isolated anti-HBc IgG positive persons (HBsAg negative, anti-HBc positive and anti-HBs negative profile), vaccination should be discussed on an individual level. However, if anti-HBc results are not available, HBV vaccination is recommended in all HBs-Ag negative persons. In persons vaccinated for HBV with insufficient response (anti-HBs < 10 IU/L), re-vaccination should be considered. The use of the more immunogenic vaccine Heplisav B should be evaluated where available (off-label). Double-dose (40 µg) at 3-4 time points (months 0, 1, 2 and 6) may help to improve response rates to the HBV vaccine. Persons who fail to seroconvert after HBV vaccination and remain at risk for HBV should have annual serological tests for evidence of HBV infection. TDF based cART has been associated with prevention of HBV infection in these persons and ART including TDF or TAF is recommended



EACS Guidelines Version 12.0.1; Oct 2023

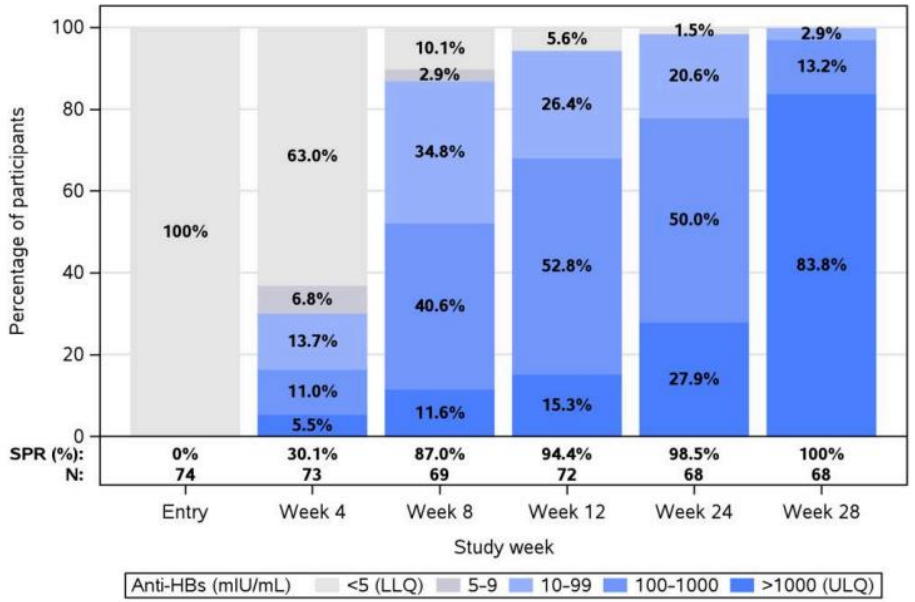
Immunogenicity and Safety of Hep B vaccine with a Toll-like Receptor 9 Agonist Adjuvant (HEPLISAV-B) in HBV Vaccine-naive People with HIV

Study design: Multicentric international open-label study

Inclusion criteria: vaccine-naive; 18-70 y; ART; CD4>100/µl; HIV-RNA< 1000 copies/ml

Vaccine schedule: Heplisav B at W0, W4, W24

Results: all 68 participants reached seroprotective titer after receiving 3 vaccine doses



Marks M K et al. CID 2023 Apr 5:ciad201.

HepB-CpG Vaccine Is Superior to HepB-alum in People With HIV and Prior Vaccine Nonresponse: A5379

A5379 (BEeHIVe) Study Design

Phase III, prospective, open-label, interventional, two group study being conducted at US and non-US sites

Group B – No prior HBV vaccination (n=73)

- Participants receive HepB-CpG 3 doses at entry and at weeks 4 and 24.

Group A – Non-response to conventional vaccine (n=561)

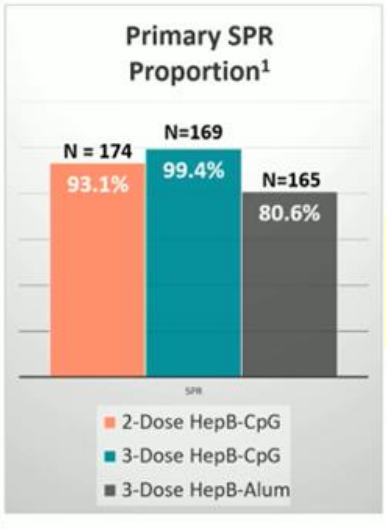
- Participants randomized 1:1:1 to receive
  - **HepB-CpG 2 doses** at entry and week 4 (n=187)
  - **HepB-CpG 3 doses** at entry and at weeks 4 and 24 (n=187)
  - **HepB-alum** (Engerix®) 3 doses at entry and at weeks 4 and 24 (n=187).
- Group A stratified by sex at birth and diabetes
- Participants on study for 72 weeks

HepB-CpG administered IM as 0.5 mL dose (contains 20 mcg of HBsAg and 3000 mcg CpG 1018® adjuvant)
HepB-alum administered as 1.0 ml dose (contains 20 mcg of HBsAg)

Marks K et al, CROI 2024;#209

Results:

» **Of the 561 eligible participants enrolled at 41 sites from 10 countries: 64% were male, 42% Black, 35% White, 17% Asian, 22% Hispanic. Median age was 46 years (range 18-70), 56% enrolled in the US, 21% Africa, 17% Asia, 6% S. America. Median CD4 was 638 cells/mm3, 94% had HIV-1 RNA <40 copies/ mL, 29% BMI >30, and 13% diabetes. 96% completed all prescribed doses.**

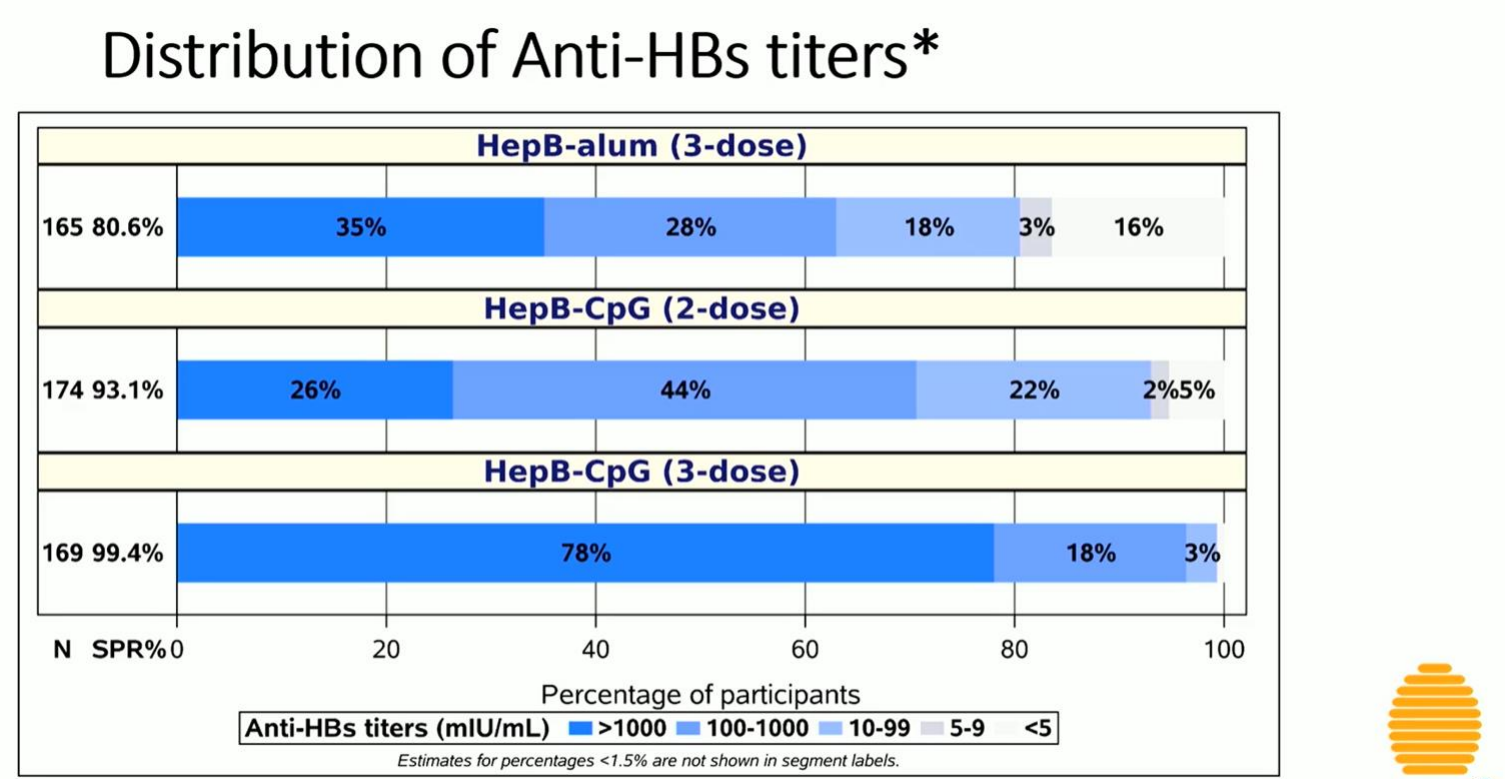


A sensitivity analysis that included participants with imputed results showed SPR:
92.3% (n=182), 99.4% (n=181), and 77.8% (n=180).

Primary SPR Endpoint
Seroprotection response (SPR) defined as anti-HBs ≥10 mIU/mL at Week 28 in 3-dose arm and Week 12 in 2-dose arm

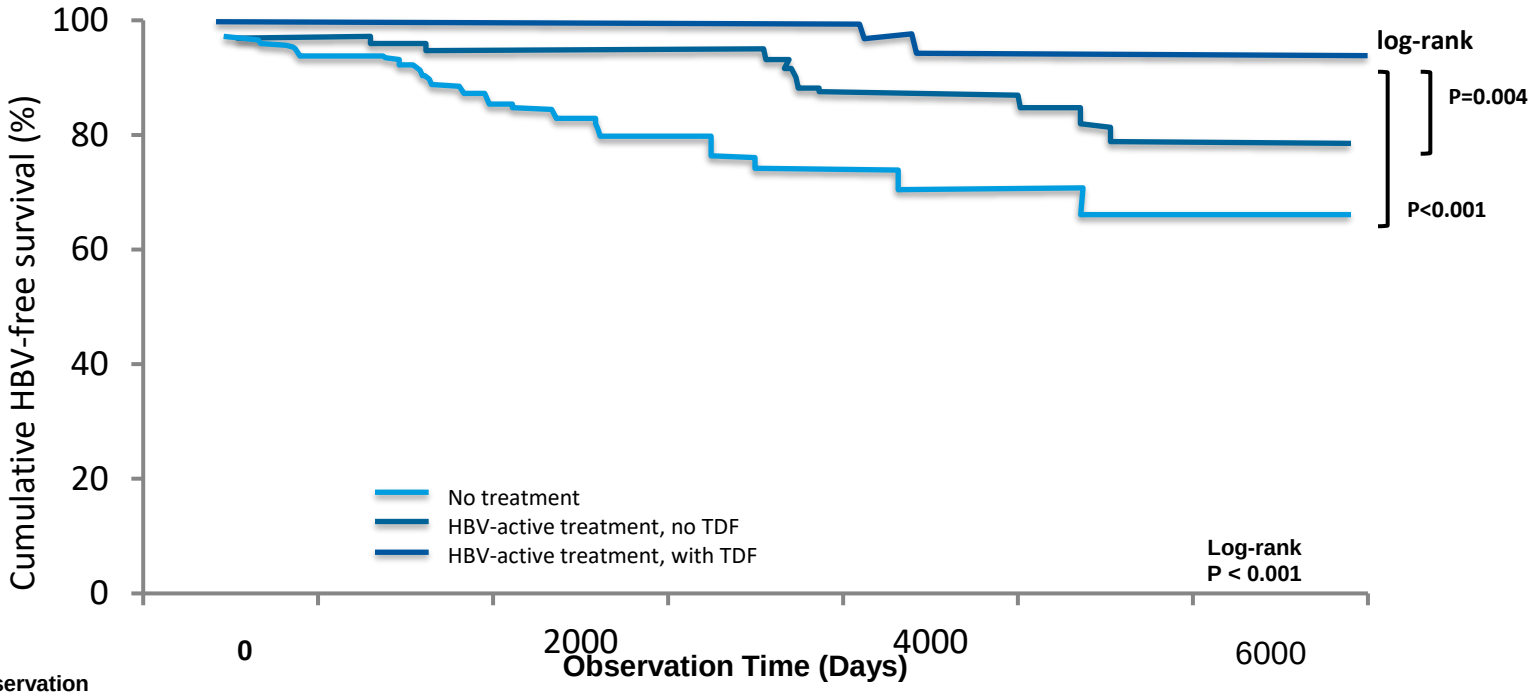
Marks K et al, CROI 2024;#209

Results:



*Anti-HBs titers corresponding to the primary endpoint timepoint

Kaplan–Meier:
HBV-free survival (MSM)



Numbers in observation				
No treatment	107	50	19	8
Treatment, no TDF	86	67	36	16
Treatment, with TDF	189	49	38	12

Brinkman K et al. CROI 2013; O#33;
Heuft MM et al., AIDS 2014;28:999–1005

BRIEF REPORT

Hepatitis B infection or reactivation after switch to two-drug antiretroviral therapy: A case series, literature review, and management discussion

Vasishta, Shilpa MD[1,3]; Dieterich, Douglas MD[2]; Mullen, Michael MD[1]; Aberg, Judith MD[1]

Author Information

JAIDS Journal of Acquired Immune Deficiency Syndromes
():10.1097/QAI.0000000000003239, June 21, 2023. | ***DOI:***
10.1097/QAI.0000000000003239

Abstract

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Acute HBV-infection after switch to LA 2DR therapy

Open Forum Infectious Diseases

BRIEF REPORT

Acute Hepatitis B Infection After a Switch to Long-Acting Cabotegravir and Rilpivirine

Claire Pintado,[1] Constance Delaugerre,[2] and Jean-Michel Molina[1]

[1]Department of Infectious Diseases, Saint-Louis Hospital, University of Paris Diderot, Paris, France, [2]Department of Virology, Saint-Louis Hospital, University of Paris Diderot, Paris, France

Maintenance antiretroviral therapy with combination of two injectable long-acting drugs, cabotegravir and rilpivirine, is a new strategy addressing the challenges of daily adherence to oral pills that has shown non-inferior efficacy to standard of care therapy in patients with suppressed HIV-infection. Patients co-infected with hepatitis B virus (HBV) are not eligible for this dual therapy since it has no activity against HBV, but this strategy should also be restricted to patients with anti-HBs antibodies since people with HIV are still at risk of HBV acquisition due to high risk behavior and since HBV vaccination does not always elicit anti-HBs antibodies, as highlighted in the case report below.

Keywords: Acute hepatitis B; Long-acting antiretroviral HIV; cabotegravir; rilpivirine; HBV vaccination

Maintenance antiretroviral therapy (ART) with injectable long-acting (LA) drugs is a new strategy that addresses the challenges of daily adherence to oral pills that have shown noninferior efficacy to standard-of-care therapy in patients with individuals at higher risk of HBV infection who either have not completed a full HBV vaccination series or lack serologic evidence of immunity [4, 5].

A 31-year-old man who has sex with men was diagnosed with HIV-1 infection in November 2016 and was enrolled in the FLAIR study—an HIV clinical trial—and started induction ART in February 2017 with dolutegravir, lamivudine, and abacavir. Laboratory tests obtained at the screening visit showed no markers of prior HBV infection (negative HBs antigen, negative HBs antibodies, and negative hepatitis B core [HBc] antibodies) and no history of HBV vaccination. Human immunodeficiency virus-1 plasma viral load became undetectable 2 months after induction therapy. In September 2017, this patient was randomized to receive LA therapy with cabotegravir and rilpivirine and was started on 4 weeks of an oral lead with cabotegravir and rilpivirine before monthly LA injections of cabotegravir and rilpivirine.

He received 3 intramuscular injections of HBV vaccine in July 2017, August 2017, and April 2018 combined with hepatitis A virus vaccination. He was treated for multiple sexually transmitted infections between December 2016 and April 2018: syphilis, urethral and anal chlamydia, and shigellosis.

In June 2018, at a monthly follow-up visit, increased aspartate aminotransferase (78 IU/L) and alanine aminotransferase (ALT) levels (162 IU/L) were documented for the first time in

Safety and Tolerability Results of Oral Weekly ISL + LEN Over 24 Weeks

Grade 3/4 Laboratory Abnormalities

Participants with laboratory abnormalities, n (%)[a]	ISL + LEN (n=52)	B/F/TAF (n=52)
Grade 3	**5 (9.6)**	**4 (7.8)**
Increased ALT	1 (1.9)	0
Increased creatinine	1 (1.9)	0
Decreased creatinine clearance	2 (3.8)	2 (3.9)
Fasting hyperglycemia	0	1 (2.6)
Non-fasting hyperglycemia	1 (2.5)	2 (4.9)
Hyperkalemia	1 (1.9)	0
Glycosuria	1 (1.9)	2 (3.9)
Grade 4	**1 (1.9)**	**0**
Increased creatine kinase	1 (1.9)	0

No Grade 3 and 4 laboratory abnormalities were clinically significant, except ALT elevation seen in a participant with acute hepatitis B

[a]Denominator in % calculation is the total participants in each group with a postbaseline value for the given measurement type.
ALT, alanine transaminase; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; ISL, islatravir; LEN, lenacapavir

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Colson AE, et al. CROI 2024, Oral 208

Use of Dual ARV Therapy in individual with different HBV serological patterns

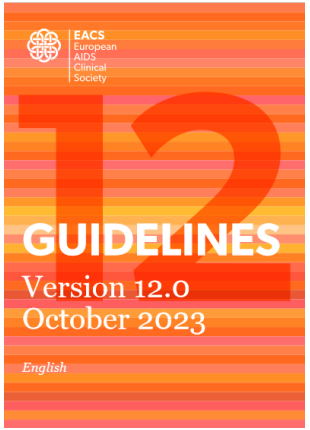
- **HBs-Ag positive**
- **Anti-HBc-positive**

Chronic Hepatitis B

Treatment of HBV/HIV Coinfection

Treatment indication

1. All persons with HBV/HIV co-infection should receive ART that includes TDF or TAF unless history of tenofovir intolerance
2. Stopping anti-HBV active ART should be avoided in persons with HIV/HBV co-infection because of the high risk of severe hepatitis flares and decompensation following HBV reactivation hepatitis



EACS guidelines version 12.0 2023

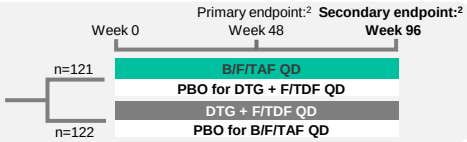
ALLIANCE: Phase 3, randomized study (subgroup analysis)

Factors Associated With HBV Response to B/F/TAF Versus DTG + F/TDF at Week 96 in People With Both HIV and HBV[1]

In Germany, B/F/TAF is only indicated for the treatment of HIV.

N=243

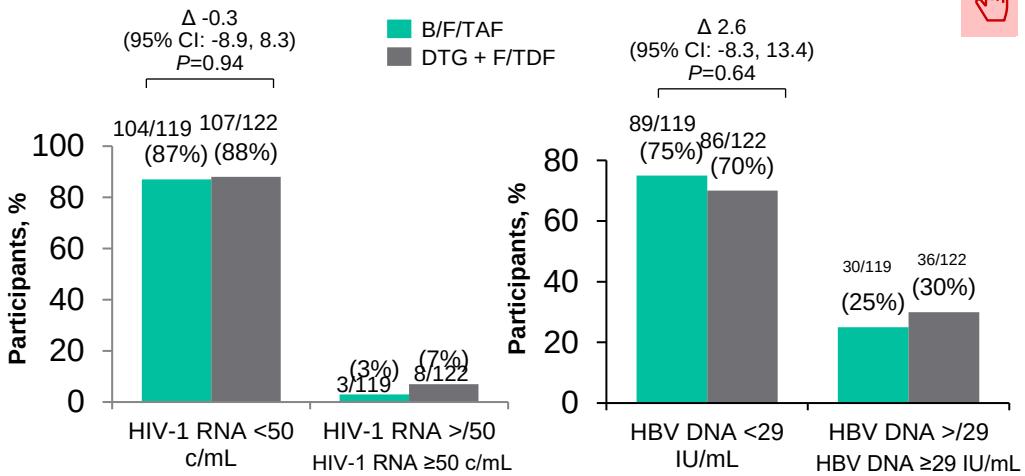
Adults with both HIV-1 and HBV; no previous HIV-1/HBV treatment[a]



Outcome

Treatment difference in the proportion of participants with HBeAg loss or seroconversion and ALT normalization at Week 96, by subgroup

HIV RNA Suppression and HBV DNA Suppression at Week 96[3]



Overall difference in proportion of participants with HBeAg loss: 18.1% (95% CI: 5.2, 31.0); B/F/TAF: 38%; DTG + F/TDF: 20%[1]

Factors associated with significantly higher rates of HBeAg loss with B/F/TAF versus DTG + F/TDF at Week 96[1]	
Asian race	Lower HIV-1 viral load (baseline HIV-1 RNA ≤100,000 c/mL)
Younger age (<30 years)	Higher CD4 levels (baseline CD4 count ≥200 cells/μL)
Higher study drug adherence (≥95%)	Asymptomatic HIV-1 at baseline
Lower HBV viral load (baseline HBV DNA <8 $\log_{10}$ IU/mL)	Lower HBV levels at Week 48 (HBV DNA <29 IU/mL)
HBV genotype B/C	Abnormal ALT levels at Week 12
Abnormal baseline ALT levels (>ULN)	No treatment-emergent Grade ≥3 ALT elevations by Week 12

Treatment differences were comparable for **HBeAg seroconversion**

Consistent with the overall population, B/F/TAF was associated with significantly higher rates of HBeAg loss and seroconversion at Week 96 compared with DTG + F/TDF in multiple subgroups

[a]HIV-1 RNA ≥500 c/mL; HBV DNA ≥2000 IU/mL; sensitivity of HIV-1 to FTC and TFV; $eGFR_{CG}$ ≥50 mL/min

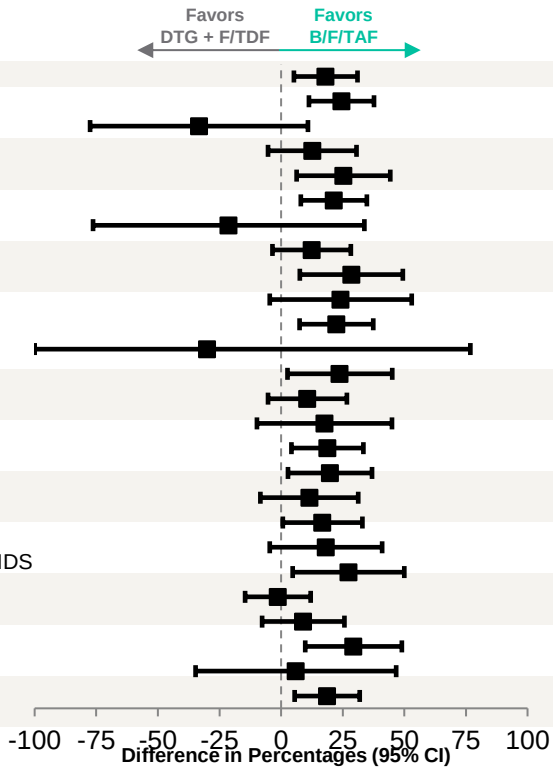
HBeAg, hepatitis B e antigen; PBO, placebo

1. Avihingsanon A, et al. CROI 2024, Poster 732; 2. NCT03547908. https://classic.clinicaltrials.gov/ct2/show/NCT03547908 (accessed March 23, 2024); 3. Avihingsanon A, et al. *Lancet HIV*. 2023;10:e640-52

ALLIANCE: Phase 3, randomized study (subgroup analysis)

Treatment Difference in Proportion of Participants with HBeAg Loss at Week 96, by Subgroup[a]

In Germany, B/F/TAF is only indicated for the treatment of HIV.



		n/N (%)		Difference in %
		B/F/TAF	DTG + F/TDF	(95% CI)
Overall		34/90 (38)	19/97 (20)	**18.1 (5.2, 31.0)**
Race	**Asian**	32/82 (39)	12/84 (14)	**24.5 (11.3, 37.7)**
	Non-Asian	2/8 (25)	7/13 (54)	-33.3 (-77.5, 10.9)
Age, years	≥30	18/49 (37)	13/54 (24)	12.7 (-5.3, 30.6)
	<30	16/41 (39)	6/43 (14)	**25.3 (6.3, 44.3)**
Study drug adherence	**≥95%**	32/81 (40)	16/89 (18)	**21.4 (8.0, 34.8)**
	<95%	2/9 (22)	3/7 (43)	-21.3 (-76.3, 33.8)
Baseline HBV DNA, IU/mL	≥8 $\log_{10}$	19/56 (34)	14/65 (22)	12.4 (-3.5, 28.3)
	<8 $\log_{10}$	15/34 (44)	5/32 (16)	**28.5 (7.6, 49.4)**
HBV genotype	A/D	9/18 (50)	8/30 (27)	24.2 (-4.6, 53.0)
	B/C	23/63 (37)	8/59 (14)	**22.5 (7.5, 37.4)**
	Other	1/5 (20)	1/2 (50)	-30.0 (-100.0, 76.8)
Baseline ALT (AASLD)	**>ULN**	21/43 (49)	9/36 (25)	**23.8 (2.6, 45.1)**
	≤ULN	13/47 (28)	10/61 (16)	10.7 (-5.3, 26.7)
Baseline HIV-1 RNA, c/mL	>100,000	11/24 (46)	8/28 (29)	17.6 (-9.8, 45.0)
	≤100,000	23/66 (35)	11/69 (16)	**18.8 (4.2, 33.4)**
Baseline CD4, cells/µL	**≥200**	26/59 (44)	13/55 (24)	**19.8 (2.8, 36.9)**
	<200	8/31 (26)	6/42 (14)	11.5 (-8.4, 31.3)
Baseline HIV-1 disease status	**Asymptomatic**	24/62 (39)	13/62 (21)	**16.8 (0.7, 33.0)**
	Symptomatic/AIDS	10/28 (36)	6/35 (17)	18.2 (-4.6, 41.0)
HBV DNA at Week 48, IU/mL	**<29 IU/mL**	29/46 (63)	11/30 (37)	**27.4 (4.7, 50.0)**
	≥29 IU/mL	5/44 (11)	8/67 (12)	-1.3 (-14.6, 12.0)
Normal ALT at Week 12 (AASLD)	Yes	13/49 (27)	8/47 (17)	9.0 (-7.7, 25.7)
	No	21/41 (51)	11/50 (22)	**29.4 (9.8, 49.0)**
TE Grade ≥3 ALT by Week 12	Yes	9/15 (60)	7/13 (54)	6.0 (-34.7, 46.7)
	No	25/75 (33)	12/84 (14)	**18.7 (5.5, 31.9)**

[a]Red font indicates groups with a significant treatment difference

AASLD, American Association for the Study of Liver Diseases; HBeAg, hepatitis B e antigen; TE, treatment-emergent

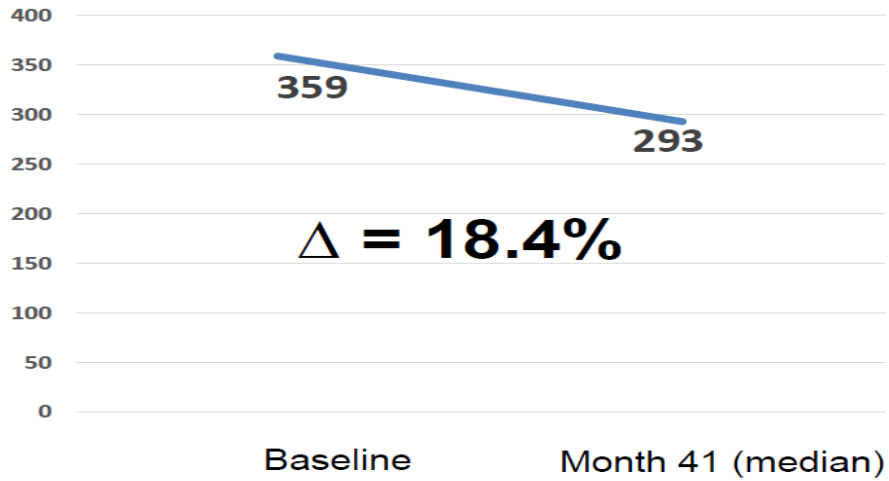
Avihingsanon A, et al. CROI 2024, Poster 732

Results: HBV SEROCONVERSION IN HBV/HIV

Table 2. Follow-up characteristics

	n=359
Median follow-up [years] (IQR)	11 (10-12)
Median CD4 T cell gain [/ul] (IQR)	188 (130-229)
Median time to HBsAg loss [months] (IQR)	41 (33-60)

Figure 3. HBsAg loss (absolute)



Patients with stage CDC C (p≤0.001), lower CD4 gain (p=0.043) and not receiving TDF/FTC (p=0.008) were less likely to lose HBsAg.

Van Bremen K et al., Liver International 2020

Use of Dual ARV Therapy in individuals with different HBV serological patterns

- **Anti-HBs-negative**
- **Anti-HBc-positive**

Past or occult HBV infection

HBV reactivation

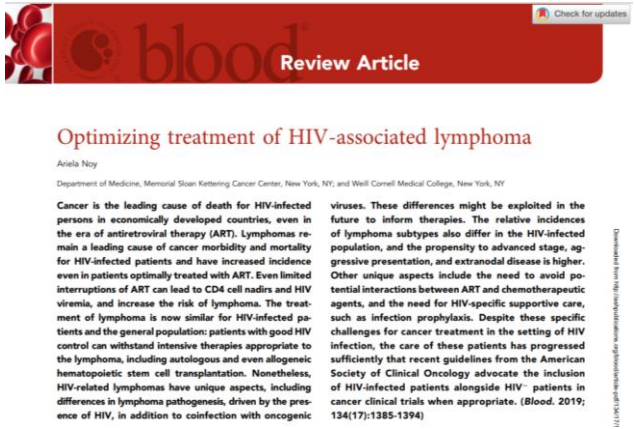
HBV reactivation

11. In HBs-Ag negative, anti-HBc positive persons undergoing immunosuppression:
    - Those treated with severe immunosuppressive therapy (chemotherapy for lymphoma/leukaemia or stem-cell or solid-organ transplantation) should receive TDF/TAF therapy to prevent HBV reactivation. For persons with other markers of possible HBV exposure including isolated anti-HBs positivity (without a history of vaccination) careful monitoring for HBV reactivation is required
    - In persons treated with B-cell-depleting agents (rituximab, ofatumumab, natalizumab, alemtuzumab, ibritumomab) TDF/TAF should be part of the ART. If TDF/TAF is contraindicated, second line options include ETV, 3TC and FTC. However, cases of reactivation due to 3TC resistance have been described
    - In those not treated with HBV-active ART who receive other immunosuppressive therapy (e.g. TNF-alpha inhibitor), careful monitoring with HBV-DNA and HBsAg is required for HBV reactivation. If this is not possible, addition of TDF/TAF is recommended

i Quantitative HBsAg < 1000 IU/mL predicts HBsAg loss

Prior to ART simplification with a regimen without TDF/TAF, HBV status should be re-checked. In PLWH with isolated anti-HBc, relapse of HBV-DNA is possible, therefore transaminases and HBV-DNA should be checked regularly. PLWH with positive HBsAg should remain on TDF or TAF containing ART

HBV reactivation:rituximab



blood

Review Article

Check for updates

Optimizing treatment of HIV-associated lymphoma

Ariela Noy

Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; and Weill Cornell Medical College, New York, NY

Cancer is the leading cause of death for HIV-infected persons in economically developed countries, even in the era of antiretroviral therapy (ART). Lymphomas remain a leading cause of cancer morbidity and mortality for HIV-infected patients and have increased incidence even in patients optimally treated with ART. Even limited interruptions of ART can lead to CD4 cell nadirs and HIV viremia, and increase the risk of lymphoma. The treatment of lymphoma is now similar for HIV-infected patients and the general population: patients with good HIV control can withstand intensive therapies appropriate to the lymphoma, including autologous and even allogeneic hematopoietic stem cell transplantation. Nonetheless, HIV-related lymphomas have unique aspects, including differences in lymphoma pathogenesis, driven by the presence of HIV, in addition to coinfection with oncogenic viruses. These differences might be exploited in the future to inform therapies. The relative incidences of lymphoma subtypes also differ in the HIV-infected population, and the propensity to advanced stage, aggressive presentation, and extranodal disease is higher. Other unique aspects include the need to avoid potential interactions between ART and chemotherapeutic agents, and the need for HIV-specific supportive care, such as infection prophylaxis. Despite these specific challenges for cancer treatment in the setting of HIV infection, the care of these patients has progressed sufficiently that recent guidelines from the American Society of Clinical Oncology advocate the inclusion of HIV-infected patients alongside HIV⁻ patients in cancer clinical trials when appropriate. (*Blood*. 2019; 134(17):1385-1394)

HIV-infected patients have an increased prevalence of viral hepatitis B. Screening for hepatitis B is particularly important prior to treatment with rituximab-containing regimens. Rituximab can lead to reactivation of latent hepatitis B virus or exacerbation of low-level infection, both leading to fulminant hepatic failure. Patients who screen positive for hepatitis B must be on antiviral therapy for hepatitis B, often accomplished with drugs that overlap with anti-HIV therapy. Care should be taken to avoid hepatitis B prophylaxis without highly active antiretroviral therapy to avoid outgrowth of resistant HIV strains. Typically, anti–hepatitis B therapy is continued for at least a year after rituximab exposure.[109]

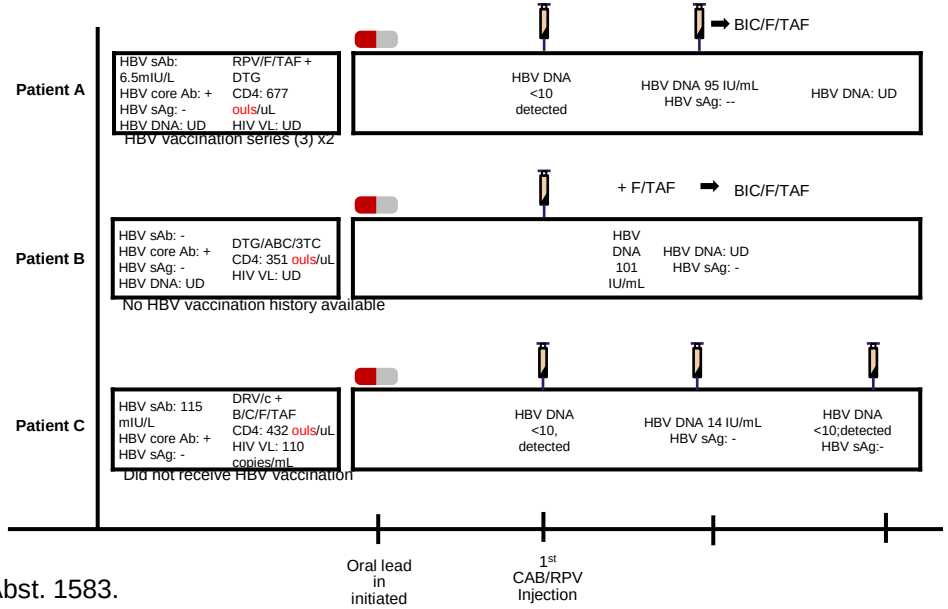
Low-level HBV Viremia After Switching to Long-Acting Injectable Cabotegravir/Rilpivirine in Patients with HIV + HBV core AB positivity and HBS-Ag negativity

149 =
switched to LAI
CAB/RPV

38 (25.5%) =
HBcAb + and HBsAG -

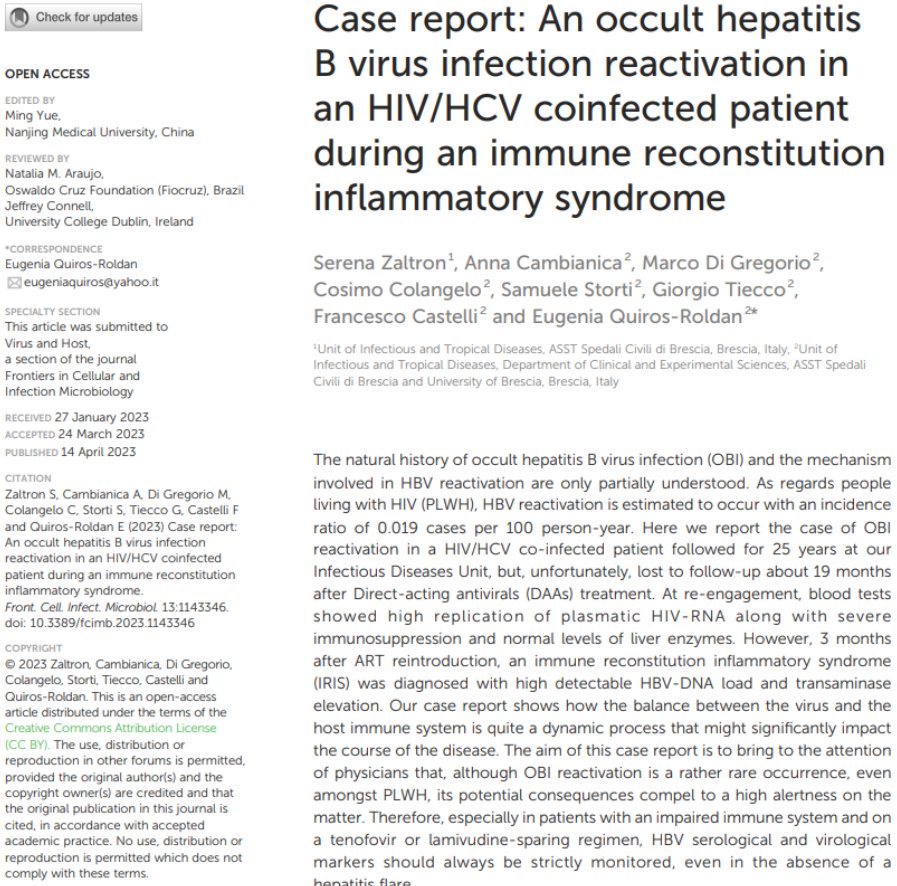
3 (7.9%) =
HBV viremia

- **Two of the patients were switched back to a TFV-containing three-drug regimen with subsequent suppression of HBV DNA levels.**
- **The third patient opted to continue LAI CAB/RBV. Repeat HBV DNA levels were detected but remained low and the patient's sAg remained negative.**
- **All patients' LFTs remained within normal limits.**



Welford E, et al. IDWeek 2022; Washington, DC; Oct. 19-23, 2022; Abst. 1583.

HBV reactivation during IRIS



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Case report: An occult hepatitis B virus infection reactivation in an HIV/HCV coinfected patient during an immune reconstitution inflammatory syndrome

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The natural history of occult hepatitis B virus infection (OBI) and the mechanism involved in HBV reactivation are only partially understood. As regards people living with HIV (PLWH), HBV reactivation is estimated to occur with an incidence ratio of 0.019 cases per 100 person-year. Here we report the case of OBI reactivation in a HIV/HCV co-infected patient followed for 25 years at our Infectious Diseases Unit, but, unfortunately, lost to follow-up about 19 months after Direct-acting antivirals (DAAs) treatment. At re-engagement, blood tests showed high replication of plasmatic HIV-RNA along with severe immunosuppression and normal levels of liver enzymes. However, 3 months after ART reintroduction, an immune reconstitution inflammatory syndrome (IRIS) was diagnosed with high detectable HBV-DNA load and transaminase elevation. Our case report shows how the balance between the virus and the host immune system is quite a dynamic process that might significantly impact the course of the disease. The aim of this case report is to bring to the attention of physicians that, although OBI reactivation is a rather rare occurrence, even amongst PLWH, its potential consequences compel to a high alertness on the matter. Therefore, especially in patients with an impaired immune system and on a tenofovir or lamivudine-sparing regimen, HBV serological and virological markers should always be strictly monitored, even in the absence of a hepatitis flare.

Use of Dual ARV Therapy in individuals with different HBV serological patterns

- **Anti-HBs-positive**
- **Anti-HBc-negative**

Successful prior HBV vaccination

Use of Dual ARV Therapy in individuals with different HBV serological patterns

- **Anti-HBs-positive**
- **Anti-HBc-negative**

- ***Dual therapy no problem at all***
- ***check anti-HBs titer regularly and revaccinate where necessary***

Summary

- **Prior to ART simplification with a regimen without TDF/TAF, HBV status should be re-checked.**
- **PLWH and HBV coinfection should receive tenofovir as part of their HIV therapy and not undergo simplification to 2DR therapy.**
- **PLWH undergoing rapid ART start and no HBV serology available at best should have tenofovir as one NRTI on board.**
- **PLWH and negative HBV serology should receive HBV vaccination**
- **in persons with isolated anti-HBc antibodies there may be a risk of viral breakthrough or relapse of HBV in some circumstances.**

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Thank you!!!