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TITLE: Risk of hepatitis B virus (HBV) infection and re-activation after discontinuation of tenofovir and/or lamivudine as part of antiretroviral therapy in a high HBV endemicity setting

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ABSTRACT BODY:

Abstract Body: Background: In HIV-positive patients, including HBV-active agents as part of antiretroviral therapy (ART) is proposed to exert a prophylactic effect against both de novo acquisition of HBV and reactivation of a previously resolved HBV infection. The aim of this study was to determine the risk of HBV infection and reactivation in HIV-positive patients who discontinued HBV-active agents (tenofovir and/or lamivudine) as part of ART in Yaoundé, Cameroon.

Methods: The study recruited 80 patients who tested HBsAg and HBV DNA negative at study entry (baseline) and discontinued tenofovir and/or lamivudine while continuing ART with a ritonavir-boosted protease inhibitor. Serum samples were collected at planned study visits (week 0, 4, 12, 24, 36, 48), stored at -80°C, and tested retrospectively for the following HBV markers: HBsAg, HBsAb, Total HBcAb, HBeAg, HBeAb (Abbott Architect platform), and HBV DNA (Abbott RealTime HBV DNA assay; lower limit of quantification 10 IU/ml). HBsAg positive results were confirmed by neutralisation. Incident HBV infection was defined by detection of HBsAg, HBV DNA, and Total HBcAb in subjects lacking HBsAg, HBV DNA, Total HBcAb and HBeAb at baseline. HBV reactivation was defined by detection of HBsAg and HBV DNA in subjects with Total HBcAb at baseline.

Results: Evidence of incident HBV infection was observed in 2/80 (2.5%) subjects at week 12 and week 24 of follow-up, respectively. One subject (all HBV markers negative at baseline) experienced acute hepatitis with markedly raised transaminases (ALT/AST 824/661 U/L) and jaundice at week 12. The second subject (baseline HBsAb 17 IU/L; all other HBV markers negative at baseline) experienced an asymptomatic infection coinciding with a modest raise in transaminases (ALT/AST 27/27 IU/L at baseline and 59/42 IU/L at week 24). HBV reactivation occurred in 2/80 (2.5%) subjects (baseline HBsAb 191 IU/L and 169 IU/L, respectively). Both incident and reactivated infections resolved following the addition of tenofovir and lamivudine to the ART regimen. CD4 cell counts in the 4 patients were median 438 cells/mm³ (range 317-734); all subjects had suppressed plasma HIV-1 RNA load (<60 copies/ml).

Conclusion: HIV-positive patients who discontinue HBV-active agents as part of ART in a setting of high HBV endemicity are at risk of both de novo HBV acquisition and reactivation of a previously resolved HBV infection. The observation does not appear to correlate with poor HIV control and significant immune suppression. HBV reactivation in the presence of HBsAb levels >100 U/L suggests possible escape from antibody neutralisation.

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Co-Author Disclosure Status

The following authors have completed their AASLD 2017 disclosure: Adam Abdullah: No Answer. | Apostolos Beloukas: No Answer. | Olga Mafotsing Fopoussi: No Answer. | Judith Torimiro: No Answer. | Charles Kouanfack: No Answer. | Anna Geretti: Disclosure completed