

Plan Overview

A Data Management Plan created using DMPTool

DMP ID: <https://doi.org/10.48321/D1GH27>

Title: High frequency of Lamivudine and Telbivudine resistance mutations in hepatitis B virus isolates from human immunodeficiency virus co-infected patients on highly active antiretroviral therapy in Bucaramanga, Colombia

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Project abstract:

Hepatitis B virus (HBV) antiviral Resistance-Associated Mutations (RAMs) in human immunodeficiency virus (HIV) coinfecting patients undergoing highly active antiretroviral therapy (HAART) are complex and incompletely understood. We aimed to determine the prevalence of HBV coinfection, HBV genotypes, and RAMs in a cohort of people living with HIV (PLWH) in the northeastern region of Colombia. This cross-sectional study was carried out between February 2013 and February 2014. Virological, immunological and HAART data were collected from clinical records. In-house nested PCR and Sanger sequencing of the HBV pol gene were used to identify coinfections, genotypes, RAMs and HBV s antigen (HBsAg) escape mutants. Among 275 PLWH, HBV coinfection was confirmed in 32 patients (11.6%), of whom nine (28.2%) were HBsAg positive (active hepatitis B), and 23 (71.8%) were occult hepatitis B infections (OBI). All HBV sequences (n = 23) belonged to the genotype F3. Among HIV/HBV coinfections, 71.9% had CD4+ T cell counts above 200 cells/mm³ and 37.5% had undetectable HIV viral loads. The RAMs rtL80I, rtL180M, and rtM204V, which confer resistance to Lamivudine/Telbivudine and partially resistant to Entecavir, were found in all HBV isolates. An unknown rt236Y mutation to Tenofovir was also identified. Most patients under HAART received first-generation HBV antiviral therapy with a low genetic barrier to resistance. Antiviral Drug-associated Potential Vaccine-escape Mutations (ADAPVEMs) in the S gene were observed in all isolates ranging from 1–20 amino acid substitutions. However, no vaccine escape mutants were detected. In Conclusion, these findings highlight the importance of HBV molecular screening, antiviral resistance monitoring and new guidelines for PLWH to overcome RAMs and prevent HBV-related liver disease.

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Copyright information:

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High frequency of Lamivudine and Telbivudine resistance mutations in hepatitis B virus isolates from human immunodeficiency virus co-infected patients on highly active antiretroviral therapy in Bucaramanga, Colombia

The present project entailed sequencing PCR fragments corresponding to the RT domain of the pol gene and involved HBV DNA sequences from individuals co-infected with HIV (PLWH). Twenty-five genomic sequences were obtained, consisting of twenty-three from patients with HBV DNA sequences who were co-infected with PLWH, and two from HBsAg-positive blood donors. These sequences were uploaded in fasta format.

PCR fragments corresponding to the RT domain of the pol gene were sequenced using the Sanger platform 3730XL (Applied Biosystems, Thermo Fisher, CA, USA). Raw HBV DNA sequences from co-infected PLWH and two HBsAg (+) blood donors without prior NRTI treatment were automatically assembled using SeqMan Ultra (DNA Lasergene v17.1). The trimmed sequences were aligned to the consensus derived from representative HBV reference sequences from NCBI using Clustal W software. Local HBV isolates were deposited in the NCBI GenBank under the accession numbers: OQ262971-OQ262995.

Each genomic sequence was uploaded to the NCBI platform with the following information

```
LOCUS      960 bp  DNA  linear  VRL 22-MAY-2023
DEFINITION Hepatitis B virus isolate polymerase gene, partial cds.
ACCESSION  OQ262995
VERSION    OQ262995.1
KEYWORDS   .
SOURCE     Hepatitis B virus
  ORGANISM Hepatitis B virus
            Viruses; Riboviria; Pararnavirae; Artverviricota; Revtraviricetes;
            Blubervirales; Hepadnaviridae; Orthohepadnavirus.
REFERENCE  1 (bases 1 to 960)
  AUTHORS  Bautista,H., Silva,J.A. and Picon,J.
  TITLE    High frequency of Lamivudine and Telbivudine resistance mutations
            in hepatitis B virus isolates from HIV co-infected patients on
            highly active antiretroviral therapy (HAART) in Bucaramanga,
            Colombia
  JOURNAL  Unpublished
REFERENCE  2 (bases 1 to 960)
  AUTHORS  Bautista,H., Silva,J.A. and Picon,J.
  TITLE    Direct Submission
  JOURNAL  Submitted (13-JAN-2023) Laboratorio de Investigaciones Biomedicas y
            bioctenologicas, Universidad de Santander UDES, Calle 70 N 55-210,
            Bucaramanga, Santander 680003, Colombia
COMMENT    ##Assembly-Data-START##
            Sequencing Technology :: Sanger dideoxy sequencing
            ##Assembly-Data-END##
```

The studies involving human participants were reviewed and approved by Ethics Committee of the Universidad de Santander. All procedures performed during the study were in accordance with the Declaration of Helsinki and the Colombian regulations on ethics in clinical research (Resolution 8430 1993).

The handling of copyright and intellectual property rights will be in accordance with the guidelines established by the University of Santander (UNDES). There are no restrictions on the reuse of third-party data, and it is anticipated that the information derived from the sequences can be used locally to understand resistance dynamics. The genomic sequences are freely accessible in the NCBI database

The datasets presented in this study were uploaded in online repositories. The names of the repository/repositories and accession number(s) can be found at: [https://www.ncbi.nlm.nih.gov/nucleotide/?term=OQ262971:OQ262995\[pacc\]](https://www.ncbi.nlm.nih.gov/nucleotide/?term=OQ262971:OQ262995[pacc]). Since the sequence information is loaded into the NCBI database, it is not expected to encounter any issues.

Access to the NCBI platform for modifications or adjustments of the uploaded sequences will be solely under the responsibility of the principal investigator. Since NCBI is a public platform, collaborators will be able to access the uploaded sequences directly from the website

The genomic sequences of the RT domain of the pol gene and the HBV DNA sequences from individuals co-infected with HIV (PLWH) are of great value because they can be utilized in future exploratory assays. NCBI's data preservation plans aim for long-term retention, which may extend for many years or even indefinitely, particularly for valuable research data

A long-term preservation plan for the dataset is in place. Given that the genomic sequences are uploaded to NCBI, they are expected to be stored for the long term, serving as a valuable resource for future research in the field of development

The datasets presented in this study were uploaded in online repositories. The names of the repository/repositories and accession number(s) can be found at: [https://www.ncbi.nlm.nih.gov/nucleotide/?term=OQ262971:OQ262995\[pacc\]](https://www.ncbi.nlm.nih.gov/nucleotide/?term=OQ262971:OQ262995[pacc]). Since the sequence information is loaded into the NCBI database, it is not expected to encounter any issues.

There are no restrictions on sharing the data derived from the sequences since they are available in the NCBI database

The principal investigator will be responsible for implementing the DMP and ensuring it is reviewed and revised. Furthermore, any modifications to the sequences uploaded to the NCBI platform will be carried out under their guidance.

No additional resources are required to deliver Data Management Plan
