Key Summary of Published Article

Chronic Hepatitis B
Simplifying Treatment Criteria

Can treatment criteria for chronic hepatitis B (CHB) be simplified to benefit more people?

Background

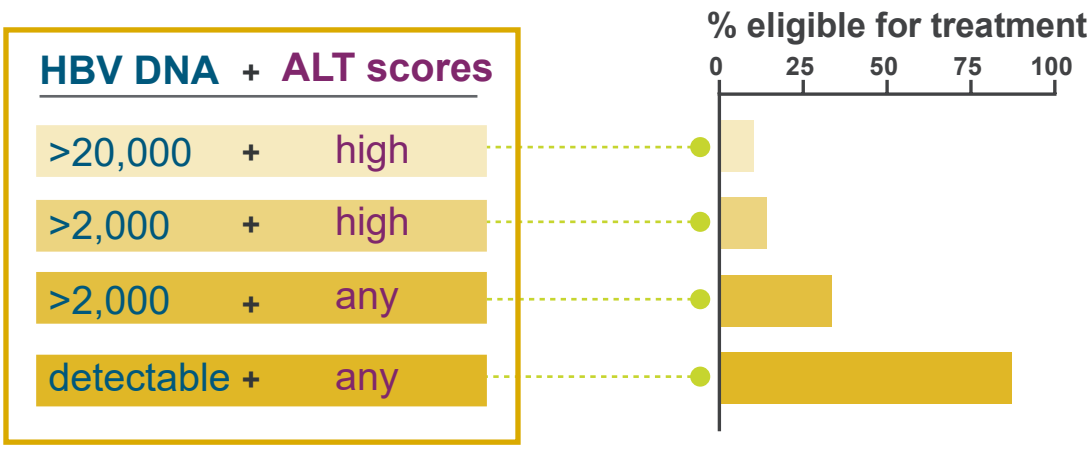
People with CHB who receive treatment early and maintain suppressed hepatitis B virus (HBV) DNA and normalized alanine aminotransferase (ALT) levels have better long-term outcomes. The complexity of current hepatitis B treatment criteria limits the use of antiviral therapy, especially at early stages when treatment can lead to better long-term outcomes.

Study design

- Retrospective analysis of deidentified laboratory test results from 2016 to 2020
- CHB = 2 HBV-positive test results ≥6 months apart
- Significant fibrosis = aspartate aminotransferase (AST) platelet ratio index >0.5

Current treatment guidelines identified 5.5% to 16.4% of patients as treatment eligible (depending on the specific guideline); of ineligible patients, 7.7% to 10.8% had significant fibrosis.

Simplifying criteria (lowering HBV DNA and ALT thresholds) would substantially increase treatment eligibility.



Simplifying treatment criteria would increase the number of people with CHB who are eligible and may help address gaps in care.

[1]Wong RJ, Kaufman HW, Niles JK, et al. Simplifying Treatment Criteria in Chronic Hepatitis B Infection: Reducing Barriers to Elimination. *Clin Infect Dis*. Published online May 20, 2022. doi:10.1093/cid/ciac385

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Article Title: Simplifying Treatment Criteria in Chronic Hepatitis B Infection: Reducing Barriers to Elimination

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doi:10.1093/cid/ciac385

Background

- As of 2016, of the estimated 292 million individuals with chronic hepatitis B (CHB), only 10% have been diagnosed and 5% of those who are treatment-eligible have received treatment.[1]
- The gaps in care are due to a variety of factors, including complexity of treatment guidelines, which delay or prevent therapy in people with significant liver fibrosis.
- **Objective:** Using data from a large US clinical laboratory, this retrospective study examined the effect of easing treatment criteria on the proportion of CHB patients who would be eligible for treatment.

Methods

- Deidentified clinical laboratory data from a Quest Diagnostics database were used to evaluate test results from patients who underwent hepatitis B testing January 1, 2016-December 31,2020.
- Patients with CHB were identified by 2 positive results from any combination of hepatitis B tests (hepatitis B virus [HBV] surface antigen [HbsAg], HBV e antigen [HbeAg], HBV DNA) performed at ≥ 6 months apart.
- Treatment eligibility was based on 4 published guideline recommendations: American Association for the Study of Liver Disease (AASLD), European Association for Study of the Liver (EASL), Asian Pacific Association for Study of the Liver (APASL), and Asian American Treatment Algorithm (AATA).
- To help identify gaps in determining treatment eligibility, patients who did not meet treatment eligibility were evaluated for significant liver fibrosis using aspartate aminotransferase to platelet ratio index (APRI >0.5).
- A simplification of antiviral treatment eligibility was developed using a 4-step lowering of HBV DNA and alanine transferase (ALT) thresholds.

Results

- CHB was identified in 84,916 patients.
- Treatment eligibility for CHB varied by guideline: AASLD, 6.7%, EASL, 6.2%, APASL, 5.8%, and AATA, 16.4%.
- However, 7.7% to 10.8% of patients who were determined to be ineligible for treatment, depending on the guideline, had significant liver fibrosis (APRI >0.5).
- Simplifying treatment eligibility criteria by lowering HBV DNA and ALT thresholds markedly increased the proportion of CHB patients eligible for treatment:
  - HBV DNA > 20,000 IU/mL + elevated ALT: 10.3%
  - HBV > 2,000 IU/mL + elevated ALT: 14.1%
  - HBV DNA > 2,000 IU/mL + any ALT: 33.5%
  - Any detectable HBV DNA + any ALT: 87.2%

Conclusions

- The findings of this study show that some patients with CHB and significant liver fibrosis may still be ineligible for treatment owing to complex guideline recommendations.
- Simplifying treatment criteria by lowering diagnostic thresholds for HBV DNA to any detectable level may help address gaps in care for patients with CHB.

Reference

1. Global prevalence, treatment, and prevention of hepatitis B virus infection in 2016: a modelling study. *Lancet Gastroenterol Hepatol*. 2018;3(6):383-403. doi:10.1016/s2468-1253(18)30056-6