Key Summary of Conference Abstract

Correlation of Quantitative Hepatitis B Surface Antigen (qHBsAg) with Hepatitis B Virus (HBV) DNA Levels as an Indicator of Viral Clearance

Background

- Quantitative testing of hepatitis B surface antigen (qHBsAg) in conjunction with HBV DNA testing may be useful in chronic HBV disease management.[1-3]
- qHBsAg testing also provides information for clinicians to monitor patient responses to antiviral therapy.[1-3]
- Although lower qHBsAg may predict HBV clearance in serum, how HBsAg secretion correlates with the transcriptional activity of HBV DNA is not fully understood.
- **Objective:** The objective of this study was to examine the association of HBsAg levels in serum with HBV DNA results using a newly developed Quest Diagnostics quantitative HBsAg assay.

Methods[a]

- Quantitative HBsAg and HBV DNA assays were conducted on 512 sera specimens (307 males; 204 females; 1 unknown) at Quest Diagnostics.
  - HBsAg assay: The investigators modified a qualitative test for HBsAg (Ortho Vitros) by transforming signal-to-cutoff ratios to quantitative values. The analytic range of the new quantitative test was 0.05 to 25,000 IU/mL.
  - HBV DNA assay: HBV DNA concentration was measured using a real-time PCR assay (Roche COBAS TaqMan) with an analytic range of 10 to 1.0 x 10^9 IU/mL.

Results[a]

- Compared to HBV DNA, the laboratory-developed qHBsAg test showed 97% sensitivity and 94% negative predictive value (NPV).
- Among patients with a negative HBV DNA result, 63% had a positive qHBsAg result.
- Specimens positive for HBV DNA had a higher median level of HBsAg than did HBV DNA-negative samples (3.2 log [IU/mL] vs 2.7 log [IU/mL]; Mann-Whitney: *P*<.0001).

Conclusions

- These results demonstrate the potential clinical utility of the Quest qHBsAg assay: high sensitivity, high NPV, and the ability to detect qHBsAg in patients with undetectable HBV DNA.
- The lower median level of HBsAg for the HBV DNA-negative group may indicate treatment-induced suppression of viral replication.
- The qHBsAg assay provides a viral-independent prognostic analyte for clinicians to follow prospectively after initiating treatment.

[a] Data updated since abstract acceptance, as reflected in the conference poster.

Poster presentation at the American College of Gastroenterology Annual Scientific Meeting

Authors
Mary L Lapé Nixon, Ron M Kagan, Dale A Schwab, Rick L Pesano, Russell E Baumann, Hollis J Batterman

Affiliation
Quest Diagnostics Infectious Disease, San Juan Capistrano, CA

American College of Gastroenterology Annual Scientific Meeting
Philadelphia, PA
October 5-10, 2018
Date and time: October 8, 2018, 10:30 AM – 4:15 PM

Webpage
https://www.eventscribe.com/2018/ACG/PosterSpeakers.asp?goToLetter=L&

References

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2. Cornberg M, Wong VW, Locarnini S, et al. *J Hepatol.* 2017;66:398-411.
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