Study Finds Noninvasive Blood Test for Liver Fibrosis May Alleviate Need for Liver Biopsies for Some Patients with Chronic Hepatitis C

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MADISON, N.J., June 8, 2009 /PRNewswire-FirstCall via COMTEX/ -- A study in the June issue of Clinical Gastroenterology and Hepatology, published by Elsevier, demonstrates that the Hepascore(TM) liver fibrosis blood-serum test panel may help physicians more accurately diagnose and stage liver fibrosis in patients with chronic hepatitis C (HCV), potentially alleviating the need for liver biopsy, the standard of care for staging fibrosis, in a particular subset of patients. The Hepascore test panel is provided exclusively by Quest Diagnostics Incorporated (NYSE: DGX), the world's leading provider of diagnostic testing, information and services.

"Hepatologists have long sought a noninvasive technique for assessing fibrosis without conducting a liver biopsy, a painful procedure that can miss cirrhosis in some patients," said Nezam H. Afdhal, M.D., study investigator and director, Hepatology, Beth Israel Deaconess Medical Center and associate professor, Medicine, Harvard Medical School. "While Hepascore is unlikely to entirely replace liver biopsy as a staging test for liver fibrosis, one can envision an algorithm using Hepascore in the management of chronic HCV. In fact, the present study suggests that a unique Hepascore-based algorithm we developed that incorporates results of FIB-4 and APRI assessments would have spared 103 of the 391 study participants with chronic HCV the need for liver biopsy, with advanced fibrosis missed in one patient. We look forward to longitudinal studies that may prospectively assess the usefulness of Hepascore in clinical strategy for monitoring, treating and possibly alleviating the need for biopsy in a subset of chronic HCV patients."

Infection with HCV most often results in chronic HCV, a liver disease. An estimated 19,000 patients were infected with HCV in the U.S. in 2006 (Source: CDC). Chronic HCV is the most common cause of liver fibrosis, a condition that can progress to liver cirrhosis or cancer. Physicians manage HCV infection based on assessments of the degree of a patient's liver fibrosis. Although liver biopsy is the gold standard for determining the degree of fibrosis in chronic HCV patients, it can cause pain, bleeding and, in rare cases, death. Biopsy also must be performed repeatedly in order to monitor fibrosis' reversal or progression. In addition, an estimated 15 to 30 percent of biopsies miss cirrhosis. Physicians typically give antiviral drug therapy to patients with significant fibrosis and monitor chronic HCV patients at low risk of developing fibrosis.

In recent years, techniques have emerged that calculate a chronic HCV patient's likelihood for fibrosis based on assessments of levels of biomarkers found in blood specimens. Most of these techniques employ an algorithm that incorporates levels of nonspecific biomarkers as well as the patient's age and gender. The Hepascore method combines assessments of hyaluronic acid (HA), a biomarker specific to liver fibrosis, with assessments of the nonspecific biomarkers bilirubin, gamma-glutamyl transferase (GGT), alpha2 macroglobulin (A2M), and age and gender.

Previous studies of Hepascore in populations in France and Australia have showed it is reliable at predicting different degrees of fibrosis in chronic HCV patients. The objective of the present study was to validate the Hepascore test in a U.S. population with chronic HCV infection, and to compare it with two indices that employ nonspecific biomarkers, aspartate aminotranaminase (AST)-platelet ratio index (APRI) and Fibrosis-4 (FIB-4). Three hundred and ninety one patients with chronic HCV infection undergoing liver biopsy were enrolled from the Liver Center at Beth Israel Deaconess Medical Center in Boston. A reference range for a negative Hepascore was also determined from a study of 214 healthy volunteers. The diagnostic performance score for Hepascore by AUROC(1) was 0.81 for significant fibrosis, 0.83 for advanced fibrosis, and 0.88 for cirrhosis.

"While Hepascore is unlikely to entirely replace liver biopsy as a staging test for liver fibrosis, our findings demonstrate the potential value of a Hepascore-based algorithm in managing chronic HCV patients," said Wael A. Salameh, M.D., study investigator and medical director, endocrinology, Quest Diagnostics Nichols Institute. "For a Hepascore value less than or equal to 0.2, significant fibrosis is unlikely and continued observation on an annual basis is sufficient. For individuals with a Hepascore equal to or greater than 0.8 with elevated FIB-4 or APRI values, therapy and cancer screening should be strongly considered."

The study is titled "Validation of Hepascore, Compared With Simple Indices of Fibrosis, in Patients With Chronic Hepatitis C Virus Infection in United States." Beth Israel Deaconess Medical Center and Quest Diagnostics Nichols Institute, the esoteric research and development testing center of Quest Diagnostics, implemented the study. Quest Diagnostics funded the study. Dr. Afdhal is a consultant who has received grant support from Quest Diagnostics.

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About Quest Diagnostics

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(1) AUROC is a graphic representation of test results that indicates a test's overall performance based on sensitivity and specificity, with a score up to 1.0. The closer a test scores to 1.0, the more accurate its performance.

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