MEDICINE AND PHARMACY NEWS

Edited by Le Minh Tan

FDA Approves First Genotyping Test for Patients With HCV

Mark Crane, Medscape Medical News, Jun 20, 2013

The US Food and Drug Administration (FDA) today approved the first genotyping test for patients with hepatitis C virus (HCV) that can better enable physicians to select the most appropriate treatment.

Using a sample of an infected patient's blood plasma or serum, the Abbott *RealTime HCV Genotype II* test can differentiate HCV genotypes 1, 1a, 1b, 2, 3, 4, and 5. Because HCV genotypes respond differently to available drug therapies, knowing the type of HCV with which a person is infected can result in better patient outcomes, the FDA said in a statement.

"Tests such as this one can help physicians gain an understanding of a patient's HCV status," Alberto Gutierrez, PhD, director of the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health, said in the statement. "Along with other clinical factors, the particular type of HCV is an important consideration in aiding health care professionals in determining if and when to initiate treatment and the appropriate type of treatment."

The new test has been approved for individuals known to be chronically infected with HCV. It is not approved for use as a diagnostic test or as a screening test for the presence of HCV genetic material in blood, blood products, or tissue donors. It has not been evaluated in newborns or pediatric patients or in patients with compromised immune systems, such as people with AIDS, the FDA said.

The FDA noted in its statement that it based its approval of the test in part on the assessment of its accuracy in differentiating specific HCV viral genotypes compared with a validated gene sequencing method. The FDA also reviewed data from investigators demonstrating the relationship between HCV genotype and effectiveness of drug therapy.

The test is manufactured by Abbott Molecular Inc, in Des Plaines, Illinois.

Novel Biomarkers Improve Diagnosis in Early RA

Alice Goodman, Jun 20, 2013

MADRID, Spain — Testing for 4 new biomarkers improves the diagnosis of early rheumatoid arthritis (RA) in patients who test negative on conventional tests.

The panel of biomarkers — UH-RA 1, UH-RA 9, UH-RA 14, and UH-RA 21 — had 85% specificity for RA. These markers were found in 36% of patients with early RA and in 24% of patients who were seronegative for rheumatoid factor and anticitrullinated protein antibody.

"It is imperative to detect the presence of RA early so that patients can be treated during the window of opportunity," said lead investigator Liesbeth De Winter, MS, from the Hasselt University in Diepenbeek, Belgium. "With early treatment, at least 50% of patients can achieve remission, yet one third of patients with RA are seronegative on tests for conventional biomarkers. The use of these novel biomarkers can improve the diagnostic yield and potentially improve outcomes."

De Winter presented the results during a news conference here at the European League Against Rheumatism Congress 2013.

In the future, it might be possible to use these biomarkers to predict the course of disease and response to therapy, she noted.

De Winter and her team tested antibody reactivity with the 4 biomarkers in 293 patients with RA, 97 healthy control subjects, and 90 rheumatic control patients with a variety of other types of arthritis.

Of the 293 RA patients, 34% were seronegative for rheumatoid factor and anticitrullinated protein antibody. Of those, 26% tested positive for the 4 biomarkers.

Negative for Conventional Markers

The biomarkers "closed the serologic gap by 8% in this study population," De Winter reported.

In addition, 13% of the 39 RA patients with a disease duration of less than 1 year tested positive for the 4 biomarkers.

Serum testing for the 4 biomarkers could be done as part of routine care for RA patients, when serum is often taken, De Winter explained, so the test will not be "too expensive."

The investigators plan to study the biomarkers in larger populations to determine the feasibility of widespread use.

News conference moderator Maya Buch, MD, from the University of Leeds in the United Kingdom, explained that "the current emphasis in the field is to diagnose patients as early as possible so we can treat to target and improve outcomes. Patients who are seronegative for rheumatoid factor and/or anticitrullinated protein antibody are at risk of being neglected."

Identifying biomarkers to enable the early diagnosis of RA will help close the gap and identify more patients who are candidates for treatment, she said. "This is an incremental step."

RA is a heterogeneous disease, Dr. Buch noted. "Probably no single biomarker will be able to identify all RA patients," she said. "It will take a multiple panel of biomarkers."

Medscape Medical News from the: EULAR Congress 2013: Abstract OP0181. Presented June 14, 2013

Blood Tests Diagnose Fibrosis, Cirrhosis in Chronic Hepatitis C

Reuters Health Information, Will Boggs, MD, Jun 04, 2013

NEW YORK (Reuters Health) Jun 04 - Several blood tests, alone and in combination, can diagnose hepatitis C virus (HCV)-related fibrosis or cirrhosis, a systematic review indicates.

The blood tests might not be as good for ruling out the conditions, however. "We found that a number of indices performed similarly well for identifying HCV patients with clinically significant fibrosis or cirrhosis," Dr. Roger Chou told Reuters Health in an email. "Relatively simple tests based on a few commonly obtained (and relatively inexpensive) lab tests were about as accurate as indices based on more tests, tests not commonly obtained, and proprietary panels."

The aspartate aminotransferase-platelet ratio index, or APRI, one of the most studied of the indices, is based on two common lab tests (AST and platelet count), and would be a reasonable option, said Dr. Chou, from Oregon Health & Science University in Portland.

As part of a review commissioned by the Agency for Healthcare Research and Quality on HCV screening, Dr. Chou and Ngoc Wasson reviewed the evidence on the accuracy of blood tests to diagnose fibrosis in patients with chronic HCV infection.

Their June 4 Annals of Internal Medicine report included 172 studies and four subsequent reports from three of these studies. Fifteen studies were rated as good quality, five as poor quality, and the remainder as fair quality.

For fibrosis, the following yielded median specificities greater than 0.9, positive likelihood ratios from 5.1 to 10, and negative likelihood ratios from 0.48 to 0.81: a platelet count <163,000, an age-platelet index score of 6.0 or greater, an APRI score >1.5, a FibroTest score >0.70, and a Forns index score >6.9.

For cirrhosis, an APRI score >2.0 was associated with a specificity of 0.94, whereas platelet counts <155,000, age-related platelet index scores of 6.0 or greater, and Hepascores <0.801 were associated with median specificities ranging from 0.86 to 0.88. Positive likelihood ratios for these tests ranged from 5.1 to 8.0, and negative likelihood ratios ranged from 0.25 to 0.55.

Only the FibroIndex and FibroTest were associated with negative likelihood ratios for fibrosis in the moderately useful range (0.10 to 0.20), the researchers note, "suggesting that blood tests may be somewhat more useful for ruling in than ruling out fibrosis."

In direct comparisons of various tests for fibrosis and cirrhosis, the differences were small or nonexistent, but in various studies, diagnostic accuracy was somewhat higher for combinations of indices.

"Factors that may affect use or selection of blood tests include availability and cost, given the variability in component blood tests, the number of tests required, and proprietary status," the authors wrote. "Studies that evaluate the virologic and clinical outcomes of antiviral treatment in HCV-infected patients who have not had liver biopsy are needed to further define optimum work-up strategies."

"If clinicians implement the CDC recommendations to perform HCV screening in all persons in the 'baby boomer' birth cohort, we will identify many more patients with HCV who will have to make decisions regarding antiviral therapy," Dr. Chou said. "In addition, more effective, all-oral, interferon-sparing antiviral regimens are expected to become available in the near future, so patients who have been deferring therapy due to concerns about interferon-related side effects may soon be making decisions about treatment. Information about fibrosis stage is important for knowing who is at risk for disease progression or complications related to HCV."

Dr. Chou added, "We didn't look at imaging tests which are also being used; some studies have looked at using combinations of indices which may increase the accuracy; we also need studies to evaluate how patients who receive antiviral treatment without undergoing biopsy fare compared to those who undergo antiviral treatment and had a biopsy done to help guide treatment decisions."

Dr. Jean-Pierre Zarski from Grenoble University Hospital in France, who has published research on blood tests for fibrosis, told Reuters Health by email, "These tests can be used in patients with viral hepatitis and maybe NASH (nonalcoholic steatohepatitis) for the assessment of liver fibrosis when the patient has no comorbidities and no other associated liver disease."

"We currently use FibroTest and Fibroscan and sometimes Fibrometer for assessing liver fibrosis," Dr. Zarski said. "For following patients under treatment, it's more complicated to clearly identify patients with fibrosis improvement."