Staging chronic hepatitis C in 7 categories using FibroTest and transient elastography

Poynard T et al; Staging chronic hepatitis C in seven categories using fibrosis biomarker (FibroTest™) and transient elastography (FibroScan®). J Hepatol. 2014;60:706-14.

The aim of the study was to extend the validation of FibroTest and transient elastography as markers of critical steps defined by occurrence of cirrhosis without complications (F4.1), esophageal varices (F4.2), and severe complications (F4.3): primary liver cancer; variceal bleeding or decompensation (ascites, encephalopathy, or jaundice). The updated individual data of 3927 patients including 1046 cirrhotic without complications at baseline were pooled from three prospective cohorts ("EPIC", "Paris", and "Bordeaux" cohorts). Among patients without varices at baseline, the incidence of varices at 5 years was 4.0% with a significant predictive performance of FibroTest (AUROC 0.77, p<0.001). At 10 years FibroTest was predictive of severe complications, including primary liver cancer (AUROC 0.84 p<0.0001). Similarly transient elastography was predictive of severe complications (p<0.0001). The authors conclude that FibroTest increase was associated with the occurrence of all severe complications including hepatocellular carcinoma, hepatic insufficiency, and variceal bleeding and also associated with the occurrence of esophageal varices.

Review of non-invasive methods


172 studies evaluated diagnostic accuracy of different non-invasive methods. For identifying clinically significant fibrosis, the platelet count, age-platelet index, aspartate aminotransferase-platelet ratio index (APRI), FibroIndex, FibroTest, and Forns index had areas under the receiver-operating characteristic curve (AUROCs) of 0.70 or greater (range, 0.71 to 0.86). FibroTest had the higher number of studies n=32) with high strength of evidence: fair quality, high consistency, and high precision. FibroTest was also the most frequently evaluated indices in head-to-head studies with APRI. FibroTest was associated with a higher AUROC than APRI for fibrosis (18 studies; median difference, 0.03; range, 0.07 to 0.10 ). The FibroTest was associated with a higher AUROC than FibroIndex for diagnosing fibrosis (median difference, 0.08; range, 0.02 to 0.10). Authors underlined also that liver biopsy is also subject of sampling error and other limitations which could result in underestimation in diagnostic accuracy of non-invasive methods due to misclassifications.

Independent meta-analysis of FibroTest in chronic hepatitis B


Authors review systematically studies describing the diagnostic accuracy of FibroTest for predicting CHB-related fibrosis using liver biopsy as a reference standard. 16 studies (N=2494) were included and 13 studies (N=1754) in the heterogeneous meta-analysis for liver fibrosis and cirrhosis, respectively. For significant liver fibrosis, the AUROC was 0.84 (95% CI: 0.78-0.88). At the FibroTest threshold of 0.48, the sensitivity, specificity for significant fibrosis were 61 (48-72%), 80 (72-86), respectively. For cirrhosis, the AUROC was 0.87 (95% CI: 0.85-0.90). At the FibroTest threshold of 0.74, the sensitivity, specificity were 62 (47-75%), 91 (88-93%). Even if the meta-analysis had differences, 0.08; range, 0.02 to 0.10. Authors underlined also that liver biopsy is also subject of sampling error and other limitations which could result in underestimation in diagnostic accuracy of non-invasive methods due to misclassifications.

Longitudinal follow-up of fibrosis in HBV patients treated with tenofovir


The study was conducted in Adult Asian-American patients with CHB from private medical and community-based practices, prospectively enrolled and treated with open-label TDF 300 mg once daily in a single-arm study for 48 weeks. Authors assessed responses on biochemical markers of liver fibrosis by FibroTest that was assessed at baseline and at week 48. Ninety patients were enrolled, 60% were HBeAg-positive at baseline and at week 48, 82% had undetectable HBV DNA and 66% ALT in normal range. The percentage of patients with F0 (no or minimal) fibrosis by FibroTest increased from 48% to 51% and those with F4 (cirrhosis) decreased from 4% to 1%. Two patients had F3 fibrosis at baseline and both improved to F2 at week 48. Four patients had F4 fibrosis at baseline and three had improvement to F3 or F1–F2 at Week 48. No patient had aggravation to cirrhosis during the study. Once more, this longitudinal study underscores the utility of FibroTest for the longitudinal follow-up of patients undergoing long-term treatment.
FibroMax for NAFLD in obstructive sleep apnea (OSA)


FibroMax panel (SteatoTest, NashTest, and FibroTest) was used to evaluate steatosis, nonalcoholic steatohepatitis (NASH), and fibrosis in a large cohort with OSA. A total of 226 of subjects referred for suspicion of OSA were included. One third had median BMI higher than 30 kg/m2 and two thirds had moderate to severe steatosis that correlates significantly with C-reactive protein. Steatosis by SteatoTest was independently associated to triglycerides, level of insulin (HOMA-IR) and nocturnal hypoxia. Thirty-eight percent had borderline or possible NASH (N1 or N2 with NashTest). Borderline or possible NASH by NashTest was independently associated to the abdominal circumference, triglycerides, level of insulin (HOMA-IR) and metabolic syndrome. Twenty percent had advanced fibrosis and cirrhosis presumed by FibroTest. Advanced fibrosis and cirrhosis as per FibroTest was independently associated to age (more than 50 years), male gender and abnormal fasting glucose or diabetic status. Authors stressed that NAFLD is one of the mechanism participating to dysfunction in OSA, and this could be easily assessed using FibroMax panel in subjects with OSA.

Review of FibroTest in alcoholic liver disease (ALD)


Hepatic histology is the main parameter that predicts morbidity and mortality in patients with alcoholic liver disease. Non-invasive methods such as biomarker tests (e.g. FibroTest or hepatic elastography (FibroScan)) may allow diagnosing alcohol-induced liver lesion without systematic biopsy. Authors review main validations for the diagnosis and prognosis of these markers in ALD.

Polish validation of FibroTest and FibroMax in alcoholic liver disease (ALD)


The experimental group comprised 137 alcohol-dependent subjects, and the control group was consisted of 50 healthy social drinkers. The diagnostic sensitivity and specificity were: 62% and 94% for SteatoTest, 61% and 94% for FibroTest. The diagnostic power (AUC) of SteatoTest and FibroTest were 0.81 and 0.80, respectively. The probability of a positive test results (SteatoTest and FibroTest) was 10-times more likely in alcoholics than in healthy individuals. Authors concluded that SteatoTest and FibroTest can be useful diagnostic tools for the detection of liver steatosis and fibrosis in excessive alcohol consumers.
Comparative validation of FibroTest with transient elastography and APRI

Castera L, et al. Comparison of transient elastography (FibroScan), FibroTest, APRI and two algorithms combining these non-invasive tests for liver fibrosis staging in HIV/HCV coinfected patients: HIV Med. 2014;15:30-9

Authors compared the performances of transient elastography (TE), FibroTest (FT), the aspartate aminotransferase-to-platelet ratio index (APRI) and two algorithms combining TE and FibroTest (Castera) or APRI and FibroTest (Sebastiani) in HIV/HCV co-infection. One hundred and sixteen HIV/HCV-coinfected patients enrolled in two French multi center studies (HEPAVIH cohort and FIBROSTIC) were included taking liver biopsy as a reference. For advanced fibrosis, both TE and FibroTest (AUROC = 0.87 and 0.85, respectively) had a better diagnostic performance than APRI (P < 0.005). Authors concluded that in HIV/HCV-coinfected patients, TE and FibroTest have a similar diagnostic accuracy for significant fibrosis. The use of the SAFE and Castera algorithms does not seem to improve diagnostic performance.

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