

EASL
2013

FibroTest & FibroMax Scientific Publications

Key publications for 2013

de Lédinghen
2013
FibroTest HBV

FibroTest : a prognosis also in HBV

Non-invasive tests for fibrosis and liver stiffness predict 5-year survival of patients chronically infected with hepatitis B virus. *Aliment Pharmacol Ther.* 2013 Apr 5

Authors proposed to evaluate the 5-year prognostic value of FibroTest, liver stiffness by transient elastography, and other non-patented tests for liver fibrosis (APRI, FIB-4), and liver biopsy, in a prospective cohort of 600 patients with chronic hepatitis B. Survival was significantly decreased in patients diagnosed with severe fibrosis, whatever either by FibroTest or liver stiffness ($P < 0.0001$), or liver biopsy ($P = 0.02$). The 5-years overall survival as per FibroTest in patients without cirrhosis was 97%, but only 49% in patients with cirrhosis. FibroTest had a high significant prognostic value without differences with transient elastography but with superior applicability in decompensated patients with ascites. Noninvasive prognostic tools as FibroTest may help physicians to early assess prognosis and specific treatments, such as liver transplantation.

Poynard
2013
vs. ShearWave

FibroTest compared to transient and supersonic elastography

Liver fibrosis evaluation using real-time shear wave elastography (SWE): Applicability and diagnostic performance using methods without a gold standard. *J Hepatol.* 2013 Jan 12.

The aim was to compare the applicability (the measurement of reliable results) and performances of SWE for the diagnosis of fibrosis as compared with FibroTest and liver stiffness by transient elastography applying a methodology without gold standard. FibroTest applicability was 98%, significantly higher than that of both imaging methods: SWE (90%) or transient elastography (91%). Despite a lower SWE applicability of FibroTest, it was greater than that of TE in patients with ascites. The best performances for early stages were for FibroTest; SWE had a low performance for discrimination between F0 and F1. Performances for the diagnosis of cirrhosis were similar between FibroTest, LSM and SWE when elastography.

Poynard
2013
FibroTest
ActiTest

FibroTest-ActiTest improved during maintenance therapy

Improved Inflammatory Activity With Peginterferon Alfa-2b Maintenance Therapy in Non-cirrhotic Prior Nonresponders: a Randomized Study. *J Hepatol.* 2013 Mar;58(3):452-9.

EPIC-3 included patients with F2-F3 METAVIR fibrosis scores who failed retreatment and that were randomized to PegIFN alfa-2b (0.5 microg/kg/week) or observation for 36 months. Repeated blinded liver biopsies were obtained before retreatment and after maintenance therapy and concomitantly FibroTest and ActiTest. Using semi-quantitative paired biopsy, despite that maintenance therapy does not significantly improve fibrosis stage compared with observation, however, significantly more patients receiving PEG-IFN alfa-2b experienced an improvement in necroinflammatory activity as assessed by paired biopsies. Using continuous scores as FibroTest significantly more observed patients showed a worsening in fibrosis score compared with those receiving PEG-IFN alfa-2b. Similarly, using ActiTest equivalence, more patients receiving PEG-IFN alfa-2b showed improvement in activity grade compared with the observation group. Both FibroTest and ActiTest were significantly improved during maintenance therapy of patients with baseline F2-F3 METAVIR fibrosis.

Grattagliano
2013
FibroMax
Screening

FibroMax utility in the general practice

Utility of noninvasive methods for the characterization of nonalcoholic liver steatosis in the family practice. The "VARES" Italian multicenter study. *Ann Hepatol.* 2013 Jan-Feb;12(1):70-7.

A multicenter national study named « VARES » was entirely conducted in a family medicine setting within the Italian College of General Practitioners (GP). A total of 259 subjects were included by GPs, aged between 18 and 65 years old, with ultrasound and/or clinical features of non-alcoholic fatty liver disease (NAFLD) with a control group of 23 lean matched healthy subjects. According to FibroMax 70% had moderate to severe steatosis as per SteatoTest, 13% had severe fibrosis F3-F4 as per FibroTest and 6.6% inflammation as per NashTest. FibroTest significantly discriminate NAFLD patients with severe fibrosis F3-F4 from controls (no or minimal fibrosis). Multivariate analysis identified age older than 50 years, diabetes, elevated transaminases and waist circumference or obesity as highly significant independent factors for fibrosis. In severe fibrosis F3-F4 as per FibroTest patients, liver biopsy confirmed fibrosis. In conclusion, FibroMax emerges as a promising tool to evaluate liver disease staging with a key role of GPs in this respect.

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FibroTest & FibroMax Scientific Publications

Key publications for 2013

de Lédinghen
2012
Diabetes

Diabetics screened with FibroTest

Screening for liver fibrosis by using FibroScan and FibroTest in patients with diabetes. *Dig Liver Dis.* 2012;44:413-8.

The Bordeaux team has made a non-invasive detection of severe liver fibrosis using FibroTest and liver stiffness measurement (LSM) in 277 diabetic patients hospitalized. This study showed a high prevalence of severe fibrosis in patients hospitalized with diabetes, especially in patients aged 50 years or older with type 2 diabetes or with a history of diabetic foot.

Fouad
2012
SteatoTest

SteatoTest in HCV with steatosis

Noninvasive assessment of hepatic fibrosis in Egyptian patients with chronic hepatitis C virus infection. *World J Gastroenterol.* 2012 Jun 21

This study evaluated the SteatoTest from the FibroMax panel of blood tests for the noninvasive diagnosis of steatosis in 44 patients with chronic HCV and liver biopsy. There was a significant positive correlation between the percentage of steatosis evaluated by SteatoTest and by liver biopsy ($r = 0.952$, $P = 0.0001$). The authors stressed the limits of ultrasound evaluation of steatosis as almost one third of patients with histological steatosis had no steatosis on ultrasound and almost half of patients without ultrasound steatosis had mild to moderate steatosis on biopsy. In conclusion, the authors recommend FibroMax for steatosis assessment along fibrosis and activity (by SteatoTest, FibroTest and ActiTest, respectively) in patients with HCV and steatosis.

Flores-Calderón
2012
FibroTest

FibroTest in children with steatosis

Non-invasive markers of liver fibrosis in chronic liver disease in a group of Mexican children. A multicenter study. *Ann Hepatol.* 2012;11:364-8.

68 children of mean age 10 years (1-17 years) with chronic liver diseases, mainly steatosis, autoimmune hepatitis, biliary atresia and metabolic diseases were included with FibroTest, APRI and biopsy. The diagnostic value (AUROC) of FibroTest for advanced fibrosis (F3F4) was 0.90. Based on these results the authors propose the FibroTest to select patients for biopsy, fibrosis screening before clinical and biological signs and follow patients longitudinally.

Zarski
2012
FibroTest

FibroTest in multicentre independent Fibrostar study

Comparison of nine blood tests and transient elastography for liver fibrosis in chronic hepatitis C: the ANRS HCEP-23 study. *J Hepatol.* 2012 Jan

This ANRS HCEP-23 study compared the diagnostic accuracy of nine blood tests including FibroTest and transient elastography to assess liver fibrosis vs. liver biopsy, in untreated patients with chronic hepatitis C (CHC) in 19 French University hospitals. Main advantages of the study compared to previous validations were that the biopsy was reviewed by two experienced pathologists and performances were assessed using ROC curves corrected by Obuchowski's method in order to avoid spectrum bias effect. 22% patients had not applicable (failure or unreliable) elastography by Fibroscan results. Among nine noninvasive markers FibroTest AUROC was 0.84 being as accurate as the transient applicable elastography (AUROC 0.84) and two other noninvasive patented methods and significantly better than APRI, Fib-4 and Hyaluronate.

J Hepatol
Editor's Pick
Poynard
2012
FibroTest

Fibrosis progression: 342,346 FibroTests

Validation of liver fibrosis biomarker (FibroTest) for assessing liver fibrosis progression: Proof of concept and first application in a large population. *J Hepatol.* 2012;57:541-8.

September 2012, the Journal of Hepatology Editor pick: 342,346 FibroTests in the world to study the factors of fibrosis progression to cirrhosis. The fastest growth is associated with alcoholic liver disease in men - a 10-year advanced risk compared to women - the slower for women with non-alcoholic fatty liver disease. Other factors associated with progression to cirrhosis are co-infection with HIV-HCV and residency in the Middle East or Eastern Europe.

Poynard
2012
FibroTest

Liver biopsy grey zone

Liver biopsy analysis has a low level of performance for diagnosis of intermediate stages of fibrosis. *Clin Gastroenterol Hepatol.* 2012;10:657-63.e7

We examined whether the performance of non-invasive tests such as FibroTest for the diagnosis of intermediate stages of fibrosis (F2vsF1) results from the biopsy limits even for F2vsF1. We analyzed 27,869 digitized images of virtual biopsies of different sizes (5 to 30mm) from surgical explants. The performance of the biopsy was worse for diagnosing F2 vs. F1 than for F1vsF0 or F4vsF3, even for samples of 30-mm. Contrary to what is often said, the recommendation to perform biopsy instead of a noninvasive marker for the diagnosis of intermediate stages of fibrosis is not scientifically validated.

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