

FibroTest/FibroSure Scientific Publications Oral Communications and Posters for AASLD 2015

Abstract #1041

HCV Multicentric US trials using FibroTest to diagnose cirrhosis in HCV

Twelve weeks of sofosbuvir plus ribavirin is effective for treatment of genotype 2 HCV in difficult to treat u.s. veterans with cirrhosis – Results of the VALOR- HCV study.

Samuel B. Ho I, Monto A, et al.

FibroTest is used to identify cirrhotic in an open-label study to evaluate the safety and efficacy of 12 weeks of SOF+RBV in genotype-2 HCV infected veterans.

The study was conducted at 15 U.S. VA sites: 15% of subjects were African American, 9% Hispanic, among them with vascular (71.2%) or metabolic (62.1%) comorbidities.

✓ Cirrhosis was diagnosed by FibroTest (58%), FibroScan (26%), biopsy (12%), and imaging (5%).

VALOR- HCV is the largest prospective study of SOF+RBV in GT2 cirrhotic and confirms the effectiveness of all-oral SOF+RBV for 12 weeks in this difficult to treat population.

Abstract # 706

HCV SVR Follow-up using FibroTest in cirrhosis

Improvement in liver disease parameters following treatment with daclatasvir + sofosbuvir and ribavirin in patients with chronic HCV infection and advanced cirrhosis.

Fontana RJ, Poordad F, Schiff ER, et al.

The study evaluated changes over time in liver disease parameters among HCV patients from ALLY-1 advanced cirrhosis cohort treated with daclatasvir +sofosbuvir +ribavirin (DCV+SOF+RBV) any HCV genotype. SVR12 according to Child Pugh (CP) class were: A 92%, B 94% and class C 56%.

✓ During the 24 weeks between baseline and SVR12, FibroTest scores, CP scores, albumin, and total bilirubin levels all demonstrated consistent trends toward improvement with no differences according to CP class

Authors concluded that SVR after DCV+SOF+RBV treatment in patients with advanced cirrhosis improved clinical and biochemical indicators of liver disease.

FibroTest/FibroSure Scientific Publications

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Abstract #1428

NASH -FibroTest is correlated with hepatic collagen in NASH

Correlations between hepatic morphometric collagen content, histologic fibrosis staging, and serum markers in patients with advanced fibrosis due to nonalcoholic steatohepatitis (NASH)

Goodman ZG, Alaparhi L, Monge F, et al.

Authors aimed to determine the relationships between hepatic collagen assessed by morphometry with disease severity evaluated by FibroTest and other non-invasive fibrosis markers, fibrosis staging (Ishak) and NAS histologic features in 429 NASH patients with advanced fibrosis enrolled in two phase 2b trials of simtuzumab, a monoclonal antibody against lysyl oxidase-like-2 (LOXL2).

✓ Hepatic collagen was directly correlated with fibrosis stage and with FibroTest, sLOXL2, ELF, APRI, FIB-4, and NFS (all $P < 0.001$) and inversely correlated with NAS score and steatosis.

Authors concluded that in advanced fibrosis due to NASH, hepatic collagen is correlated with fibrosis stage assessed semi-quantitatively and using serum fibrosis markers.

Abstract #1435

NASH -FibroTest is correlated with sLOXL2 in NASH

Serum lysyl oxidase-like-2 (sLOXL2) levels correlate with fibrosis stage in patients with nonalcoholic steatohepatitis (NASH)

Harrison SA, Goodman ZD, Ratziu V et al.

Lysyl oxidase-like-2 (LOXL2) plays a central role in liver fibrosis by catalyzing collagen cross-linkage.

Authors aimed to determine the relationships between serum sLOXL2 and disease severity evaluated with histology, FibroTest and other non-invasive markers in 474 NASH patients with advanced fibrosis enrolled in two phase 2b trials of simtuzumab, a monoclonal antibody against LOXL2. 50 healthy controls were included.

✓ sLOXL2 was correlated FibroTest and with Ishak fibrosis stage, and other scores (ELF, APRI, FIB-4, NAFLD fibrosis score and MELD)

Authors concluded that in advanced fibrosis due to NASH, sLOXL2 levels are correlated with fibrosis stage and serum fibrosis markers including FibroTest.

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FibroTest/FibroSure Scientific Publications

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Abstract # 786

Fibrotest superior to Fibroscan in prognostication for both cirrhosis and earlier stages

Comparative 10-years prognosis of Fibrotest (FT) and liver stiffness measurement (LSM) by transient elastography-(TE, Fibroscan) in 9364 chronic liver diseases (CLD) patients (Pts)

Munteanu M, Ngo Y, Perazzo H,

Authors aimed to assess comparatively prognostication performance at 10-years for validated non-invasive methods, FibroTest and LSM by Fibroscan, according to the severity of fibrosis stage. N=9364 patients with FibroTest were included consecutively, all etiologies, in a tertiary hepatology center (Pitié-Salpêtrière Hospital, Paris, France). N=2724 patients had applicable LSM.

Overall survival

✓ FibroTest discriminates between survivals that decreased in each fibrosis stage (all $p < 0.05$ vs adjacent)

✓ LSM by Fibroscan do not discriminate between survivals in early stages ($p = NS$), but only for F3 stage or more ($p < 0.05$ vs adjacent)

Survival without liver-related complications (SLD)

✓ SLD decreased with each FibroTest fibrosis stage increase (all $p < 0.05$ vs adjacent), excepted F1 versus F2

✓ SLD were discriminate as per LSM by Fibroscan only for late stages F4.2 vs F4.3 ($p < 0.001$); no difference in SLD between early stages (from F0 to F4.1, all $p = NS$) as per LSM by Fibroscan

✓ Compared directly to LSM, FibroTest is able to discriminate prognosis between all stages including cirrhosis

Authors concluded to the superiority of Fibrotest over Fibroscan in prognostication for both earlier stages and for cirrhosis.

Abstract # 1439

FibroTest is superior to Fibroscan, APRI and FIB-4 (Obuchowski comparisons)

Comparison of 16 blood and/or elastometric fibrosis tests in 5 causes of chronic liver diseases: too much? Towards a simplification

Boursier J, Ducancelle A, Leroy V et al.

A recent meta-analysis using Obuchowski method (reflecting accuracy for all F stages) evaluated 1660 patients with different etiologies, and 16 tests (13 blood tests, including elastometry by Fibroscan, APRI and FIB-4). Reference was Metavir fibrosis (F) stage by liver biopsy.

✓ In CHC, FibroTest accuracy (0.762) was superior to Fibroscan (0.754), APRI (0.742) and FIB4 (0.741)

✓ In HIV-CHC patients, FibroTest was the only test that not decreased accuracy compared to CHC;

✓ FibroTest accuracy in chronic hepatitis B and ALD is the same as in CHC.

✓ Simple blood tests (APRI/FIB4) are not adapted to NAFLD and ALD.

✓ Fibroscan fibrosis classification should be adapted to the cause.

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Abstract #739

FibroTest and HVPG

Correlation between noninvasive markers of fibrosis and the hepatic venous pressure gradient (HVPG) in patients with compensated cirrhosis due to nonalcoholic steatohepatitis (NASH).

Bosch J, Ratziu V, Rockey DC , et al.

The objective was to determine the diagnostic utility of noninvasive fibrosis markers including FibroTest, serum lysyl oxidase- like-2 (sLOXL) for the HVPG and clinically significant portal hypertension (CSPH, HVPG \geq 10 mmHg) in 241 patients with compensated cirrhosis due to NASH enrolled in a phase 2b trial of simtuzumab.

✓ Correlation of HVPG was moderate with all serum biomarkers: FibroTest, sLOXL2, ELF, NFS, APRI and FIB-4, liver stiffness by Fibroscan, but weak with histological fibrosis stage.

✓ For the prediction of CSPH, performance was similar for FibroTest, liver stiffness, ELF, NFS, APRI, FIB-4,

✓ Performances of Fibrotest did not differ according to NSBB therapy

✓ The addition of sLOXL2 to each marker did not improve significantly the performances

Authors concluded that noninvasive markers of fibrosis, including FibroTest, are correlated with HVPG in patients with compensated cirrhosis due to NASH.

Abstract #624

New validation of FibroTest in PSC

Validation of serum fibrosis marker panels in patients with primary sclerosing cholangitis (PSC) in a randomized trial of simtuzumab

Bowlus CL, Patel K, Guha IN et al.

The aim of the study was to assess in patients with PSC the performance of serum fibrosis markers FibroTest, ELF, APRI, and FIB-4 and serum sLOXL2 from the phase 2b trial of simtuzumab (N=229 included).

✓ Correlations of fibrosis stage were moderate with FibroTest, sLOXL2, ELF, and APRI ($p=0.50-0.55$), and weak with FIB-4 ($p=0.32$).

✓ For bridging fibrosis, diagnostic performance similar for FibroTest, ELF, sLOXL2, and APRI higher than FIB4

✓ For cirrhosis, diagnostic performance was similar with no differences between measures

✓ FibroTest performances did not differ according UDCA use or ulcerative colitis.

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Abstract #616

FibroTest use in IgG4 positive PSC patients with aggressive disease

Association between elevated serum IgG4 (sIgG4) concentrations and the phenotype of patients with primary sclerosing cholangitis (PSC).

Manns MP, Eksteen B, Shiffman ML, et al.

Elevated sIgG4 has been reported in up to 15% of PSC patients and is associated with a more aggressive disease.

The aim of the study was to compare the characteristics of PSC patients with elevated and normal sIgG4 enrolled in a phase 2b trial of simtuzumab. 34/234 (14.5%) had elevated sIgG4. Compared to normal sIgG4 patients, they were older, had lower serum albumin and higher platelet levels.

✓ However, the proportions of bridging fibrosis or cirrhosis, according to liver biopsy, FibroTest, sLOSL2 or other non-invasive scores were similar between groups.

Authors concluded in this clinical trial cohort, that the sIgG4 level does not have a significant impact on PSC phenotype including disease severity assessed biochemically, histologically, or according to non-invasively.

Abstract #1676

HIV-HBV co-infected follow-up using FibroTest

Noninvasive markers of liver fibrosis remain stable in the majority of hepatitis B virus and human immunodeficiency virus co-infected patients undergoing tenofovir- containing antiretroviral therapy

Boyd A, Lacombe K, Girard PM, et al.

N=168 HIV-HBV co-infected patients (French HIV-HBV cohort) enrolled prospectively initiated TDF-containing antiretroviral therapy and repeated liver fibrosis measurements (baseline and every 6-12 months) by FibroTest and/or Fibroscan. They had 62% HBeAg-positive serology and 5-years follow-up.

✓ Among patients with baseline F3-F4, 45% had stable fibrosis and 55% regressed to F0-F1-F2. Regression seemed associated with CD4+ cell count.

✓ Among patients with baseline F0-F1-F2, 61% remained stable and 39% progressed to F3-F4.

Liver fibrosis progression seemed associated to age, ALT transaminases and with AIDS-defining event. Immunosuppression influenced fibrosis regression/progression, therefore, earlier ART-initiation should be considered.