#999

2013
FibroTest
HBV

Sun, Nov 03
8:00 AM

2-years impact of entecavir (ETV) on liver fibrosis and activity as assessed by the non-invasive methods of FibroTest-ActiTest (FT-AT) and liver stiffnesse measurements (LSM) by Fibroscan in patients with chronic hepatitis B (CHB)

Fabien Zoulim1, et al. ENTEFIB Study Group, France

Background : Fibrosis-regression rate in treated chronic hepatitis B (CHB) patients was similar using Fibrotest (Biopredictive) or liver biopsy, while for liver stiffness measurements (LSM) by Fibroscan(Echosens) there was a possible overestimation related to necroinflammatory activity (NIA)(AVT 2010).

Aim : To prospectively evaluate the histological impact of a strong inhibitor of HBV-replication, entecavir motherapy at 0.5mg per day, using non-invasive methods, i.e. FibroMax (including Fibrotest, Actitest, Steatotest for estimating fibrosis, activity and steatosis) and LSM. Methods. 133-CHB monoinfected, NUC-naive patients were pre-included in 19 centers in France. Data was recorded at baseline(M0), six, and 12-months(M6,M12): viral load, Fibromax [panel of scores (0-1)] and LSM(0-75kPa). Applicability(App) was defined as after exclusion of unreliable LSM and failures. Viral response (VR) was defined as undetectable HBVDNA. Statistics included repeated measures AVOVA (Bonferroni Multiple-Comparison Tests).

Results : 116patients were included [5 lost of follow-up, 9 missing, 3 non-App Fibrotest (acute flare-up ALT>600IU/L)]. Characteristics were: age 44(19-82)yrs; 72%males; 70% anti-HBe(+); 46%Caucasian; 2.6% alcohol>20g/day; median viral load=4.6 logIU/ml; App-LSM 81%(55/68). 31%(N=36) had advanced fibrosis (AF, F2F3F4-METAVIR) and 11%(N=12) cirrhosis as per Fibrotest; 46%(N=53) significant NIA (A1A2A3- METAVIR) as per Actitest; 26%(N=21) had M0 steatosis>1% as per Steatotest. 88 patients achieved M6, 61 M12 with 64% M6-VR and 84% M12-VR. Significant NIA as per ActiTest regressed from M0 0.58(0.03) to M6 0.27(0.03,P< 0.0001) and M12 0.27(0.03,P< 0.0001 vsM0). The same was true for AF as per FibroTest: M0 0.67(0.02) vs M6 0.56(0.02,P=0.0001) and M12 0.54(0.02,P=0.002 vsM0). Among AF-patients without M6 fibrosis-regression, 43% had baseline steatosis>5% as per Steatotest compared to 0% (p=0.04) in AF-patients that regressed fibrosis. As per AF App-LSM no regression was observed vs M0 at M6[8.5(1)vs10.1(1)kPa, P=0.28] but at M12 [6.3(0.4)kPa,P=0.009 vs M0)]. M6 regressions of significant NIA and AF as per Actitest and Fibrotest were observed regardless the VR (vs non-VR) 32% vs 48%(p=0.30) and 38% vs 50% (p=0.74), respectively.

Conclusion : After six and twelve months of entecavir treatment, advanced fibrosis and activity as presumed by Fibrotest-Actitest were significantly reduced, regardless of the viral response. Fibrosis regression as per liver stiffness measurement was observed only after twelve-month treatment. Patients without fibrosis-regression after 6-months treatment had more baseline steatosis.

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#637

2013
SteatoTest
Diabetes

Sat, Nov 02
2:00 PM

Liver steatosis, presumed by SteatoTest or Controlled Attenuation Parameter (CAP), is associated to a risk of false-positive liver stiffness measurement by transient elastography in type-2 diabetic patients

Hugo Perazzo1 et al. Pitié-salpêtrière hospital, Paris, France

Background: Transient elastography(TE) with controlled attenuation parameter(CAP), based on liver stiffness measurement(LSM); FibroTest(FT), ActiTest(AT) and SteatoTest(ST) are validated non-invasive alternative to assess liver injury in NAFLD-risk patients as type-2 diabetics(T2D). Necro-inflammatory activity and steatosis might influence LSM leading to overestimation fibrosis stages. Aims:To evaluate the impact of i steatosis (SS)[>32%] on LSM in T2D patients.

Methods:142 T2D, without liver disease history, screened for fibrosis with FT were reinvestigated by FT and LSM(M and XL probes) after a median delay of 7 years. Patients with minimal fibrosis(FT<0.48-F0F1 METAVIR) at baseline and without progression during follow-up were included. Exclusion criteria were presence of advanced fibrosis(AF)[FT≥0.48] or activity[AT≥0.27] at the reinvestigation. Patients without AF as per FT(<0.48), but with AF LSM≥7.1kPa, at the reinvestigation, were supposed as false-positive of LSM(FP-LSM). SS(>32%) was defined as per ST≥0.69 or CAP≥283 dB/m.

Results:106 T2D patients with minimal fibrosis in the last 7 yrs and without necro-inflammatory activity were pre-included[54% males, age 63 yrs, median BMI 27.6(20.8- 52.8)Kg/m2,ALT 23(10-59)U/L].After exclusion of non-applicable LSM by both probes(6.6%), 99 patients were analyzed. Patients supposed to be a LSM-FP (26%) had no liver-related complications. In univariate analysis, patients considered as FP-LSM versus non-FP-LSM, had higher: BMI[32.3(21.3-49.5)vs26.5(19.6-35.2)], ST(0.64±0.17vs0.46±0.19); waist circumference (115±18vs100±11cm), thoracic fold(25±10vs19±6mm) and higher rates of SS(58%vs19%), all p<0.001. SS patients as per ST, had higher median LSM(range)[7.7(5-75)vs 5.5(3-64),p=0.02]. In logistic regression, the presence of SS, by ST[OR=6.9(95%CI 1.7-28.4);p=0.007], remained significantly associated to FP-LSM in a multivariate model adjusted for age, gender, thoracic fold, waist circumference and metabolic factors. Among 59 patients with an applicable CAP simultaneous to ST, Spearman's correlation coefficient was r=0.37, p=0.03. Supposed FP-LSM patients had also higher rates of SS by CAP(40%vs15%,p=0.04) compared to non- FP-LSM. Patients with SS as per CAP, had higher median LSM[6.5(4.4-13.6)vs 5.7(3.2-8.7)kPa,p=0.01].The high failure rate (35%) of the M probe that measures concomitantly the CAP, limited the multivariate analysis for CAP in this population.

Conclusion: In type-2 diabetic patients, the presence of severe steatosis presumed by SteatoTest was independently associated to the overestimation of liver fibrosis by liver stiffness measurement.

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#578

2013
FibroTest
Diabetes

Sat, Nov 02
2:00 PM

Liver fibrosis progression and cardiovascular-related complications in type-2 diabetes: establishment of a significant relationship in a 7-years prospective study

Hugo Perazzo1 et al. FLIP consortium

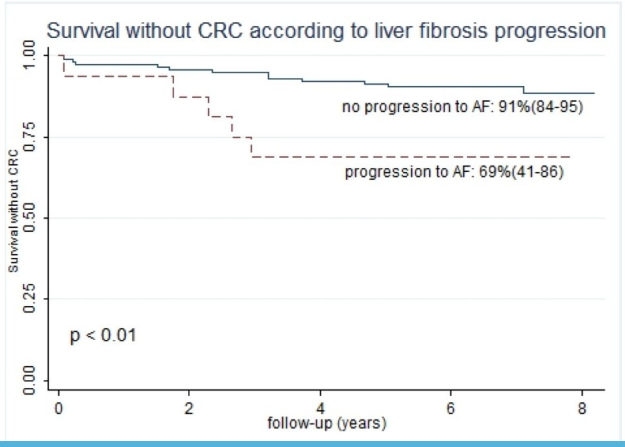
Background: FibroTest(FT), a non-invasive serum marker of liver fibrosis, has a significant prognostic value for the 5-years survival without CRC in T2D patients(1). However, no studies have evaluated the association between liver fibrosis progression and onset of new CRC.

Aim: To evaluate the relationship between liver fibrosis progression and cardiovascular-related complications in T2D patients followed during 7 years with repeated evaluation of liver fibrosis by FibroTest. Methods:627 T2D- patients with minimal fibrosis(FT<0.48 -F0F1 METAVIR) were prospectively followed[2004-2013] for CRC[myocardial infarction, unstable angina,coronary-bypass, ischemic stroke]. Liver fibrosis progression was evaluated by repeated FT during follow- up. Progression to advanced fibrosis(AF-F2F3F4) was defined by FT≥0.48 at the end of follow-up. Framingham risk score(FRS) was calculated at baseline to predict CRC risk.

Results: During the follow-up 46(7%) patients died. Among 581 alive T2D-patients with minimal fibrosis at baseline, 133(23%) had a re-evaluation of liver fibrosis and were included [56% males, age 57 yrs, BMI(range) 28.7(20.2-50.8)Kg/m2]. During a median follow-up of 6.8 yrs 16(12%) patients progressed to AF and 17(13%) patients developed CRC(26 coronary diseases;1 stroke). The survival without CRC(Kaplan-Meier mean 95%CI) was 69%(41-86) in patients who progressed to AF vs 91%(84-95) in those who did not progress(Logrank p<0.01). Progression to AF increased the risk of CRC[RR=3.8(95%CI 1.3-10.7);p<0.01). In a multivariate Cox model progression to AF remained significant after adjustment on FRS for the prediction of CRC[HR=3.8(1.3- 11.1);p=0.013].

Conclusion: In type-2 diabetics, progression from minimal to advanced fibrosis, estimated by FibroTest, was independently associated to higher incidence of cardiovascular-related complications.

References: 1 Perazzo H et al.Hepatology 2012;56(Sup S1):40A-40A



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#610

2013
FibroTest
NAFLD

Sat, Nov 02
2:00 PM

NAFLD as a contributor to early atherosclerotic lesions: a longitudinal study in 2169 asymptomatic patients at high cardiovascular risk

Raluca Pais et al. Hopital Pitie Salpetriere, Assistance Publique Hopitaux de Paris, Paris, France

Background: NAFLD increases the risk of cardiovascular (CV) events independent of the presence of traditional CV risk factors. Whether NAFLD is associated with early atherosclerotic lesions and their progression is unknown.

Aim: to evaluate the impact of NAFLD and significant hepatic fibrosis on the presence and progression of carotid intima-media thickness (CIMT) and early carotid plaques (CP), in patients (pts) at high CV risk.

Methods: Pts with >2 CV risk factors (hypertension, diabetes, dyslipidemia, obesity, active smoking), but no CV events, chronic liver disease and alcohol<50g/d underwent baseline and follow-up (f/u) carotid ultrasonography and Framingham risk score (FRS) calculation. CIMT was graded 0:normal; 1:<1 mm wall thickening without CP; 2:moderate CP (≥1-≤2.5 mm), 3:CP>2.5 mm). Progression was defined as transition to the next, higher class. Steatosis and fibrosis were assessed by the Fatty Liver Index (FLI, NAFLD present when >60), and by FibroTest (FT).

Results. 2169 patients were enrolled: 56% males, 52 year-old, BMI 25.4 kg/m2; mean FRS 12±9%, mean CIMT 0.62±0.14 mm; 40.5% had CP and 24% had a FLI≥60. Pts with NAFLD had higher CIMT (0.64±0.15 vs. 0.61±0.14 mm, p=0.001), higher prevalence of CP (30% vs. 24%, p=0.005) and higher FRS (17±9% vs. 10±8%, p<0.001). FLI was associated with baseline CIMT (p=0.002) and FLI≥60 with CP at baseline (OR=1.27, p=0.04), both independent of age, sex, smoking, diabetes and hypertension.

The median f/u was 8 yrs, 6.4 yrs in NAFLD pts and 8.5 yrs in non-NAFLD pts (p<0.001). During f/u, CIMT increased from 0.62 to 0.65 mm, p<0.001, prevalence of CP increased from 41% to 58%, p<0.001 while 38% of pts developed CP. NAFLD at baseline was associated with the progression and occurrence of CP independent of age, sex or the FRS (HR 1.30 and 1.34, respectively both p≤0.01). Among non-NAFLD pts at baseline, those who developed NAFLD during f/u had a larger increase in CIMT than those who stayed NAFLD-free.

455 pts were evaluated by FT, they were not different from the 1714 untested pts for age, BMI, CIMT and CP prevalence. 2% of these patients had a FT>0.48 compatible with bridging fibrosis. Unexpectedly, bridging fibrosis was associated with the presence of CP at baseline and with progression of CP at f/u (HR 3.83, p<0.01), both independent of FRS and FLI≥60.

Conclusion: In patients at high CV risk, NAFLD and in particular bridging fibrosis contribute to early atherosclerosis and progression thereof, independent of traditional CV risk factors.

#862

2013
FibroTest
Prognosis
HBV

Sun, Nov 03
8:00 AM

Ten-year prognostic performances of FibroTest (FT) and transient elastography (TE) in HBV chronic carriers (HBV-CC).

Thierry Poynard et al. APHP UPMC Groupe Hospitalier Pitié-Salpêtrière, Paris, France.

Background and aim

Five-year prognostic performances of baseline FT and TE have been validated in HBV- CC in two prospective cohorts, the Paris cohort (Ngo 2008) and the Bordeaux cohort (de Ledinghen 2013) for survival [overall survival (OS), and survival without liver related complications (S-LRC)]. The long-term prognostic values of FT and TE on each LRC are unknown due to the limited sample size and limited follow-up.

Patients and methods

To increase the power, we pooled the updated individual data of 2 cohorts at 10 years. Patients were included if at least 1 FT was performed at baseline, and excluded if they had other cause of liver disease. The main endpoints were survivals (S) without transplantation (LT), without liver related death (LRD), liver complications (C), primary liver cancer (HCC), ascites (A), jaundice (J), encephalopathy (SE), and variceal bleeding (VB).

Results

A total of 1295 HBV-CC with interpretable FT were included; men 68%, Caucasian 38%, SubSaharan 36%, Asian 17%; at baseline 42 years old, HBeAg 17%; active 47% and inactive 53%, 6% declared >50g alcohol/day, 24% BMI >27kg/M2. During the 10 years follow-up 598(46%) were treated (14% non-responders >2000 HBV-DNA); 76 [7.2% (95%CI 4.5-8.9)] died, 12 patients (pts) [1.2%(95%CI 0.5-1.8)] have been transplanted, 47 died from LRD [4.0%(2.8-5.2)]; the incidence of C occurring at least 6 months after FT were observed in 29 pts [Kaplan-Meir 4.5%(1.7-5.2)]: 22 HCC [4.5%(1.7-5.2)], 20 A [3.0%(1.5-4.4)], 11 J [1.3%(0.5-2.1)], 9 E [1.0%(0.3-1.7)], 5 VB [0.8%(0.0-1.5)]. A total of 792 pts had reliable baseline TE, including 657 with contemporaneous FT, which permitted direct performances comparisons. FT had significant independent prognostic values for all S and C; TE had significant prognostic values for all S with lower performances than FT except for survival without any C (Table); too few events occurred in pts with TE for estimating performances concerning A, E and VB.

Conclusion

In HBV chronic careers, FT was predictive at 10 years for each liver complications and survivals. TE had significant prognostic performance but lower than those of FT except for survival without complications.

#1434

2013
FibroTest
Prognosis
HCV

Mon, Nov 04
8:00 AM

Ten-year prognostic performances of FibroTest (FT) and transient elastography (TE) in patients with chronic hepatitis C (CHC)

Thierry Poynard et al. APHP UPMC Groupe Hospitalier Pitié-Salpêtrière, Paris, France.

Background and aim

5-year performances of FT and TE have been validated in CHC in 2 prospective cohorts, (Ngo 2006 and Vergniol 2011) for survival [overall survival (OS), and survival without liver related complications (S- LRC)]. The long-term prognostic values on each LRC are unknown due to the limited sample size and follow-up.

Patients and methods

To increase the power, we pooled the updated individual data of these cohorts at 10 years. Patients (pts) with CHC were included if at least 1 FT and 1 TE were performed, and excluded if they had other cause of liver disease. The main endpoints (estimated using Kaplan-Meier and Cox) were survivals (S) without transplantation (LT), without liver related death (LRD), LRC, primary liver cancer (HCC), ascites (A), jaundice (J), encephalopathy (E), and variceal bleeding (VB). Pts with non-reliable FT (1.8%) and non-reliable TE (18%; P=0<0.001 vs FT) were excluded.

Results

A total of 2485 pts HCV-RNA+ with FT and TE have been included, male 56%, Caucasian 71%, SubSaharan 13%, North-African 12%, Asian 18%, HIV 15%; at baseline median age 50yr old; genotype 1 62%, genotype 3 8%; 7% declared >30g alcohol/day, 17% BMI >27kg/M2, diabetes 9%; 56% METAVIR F0F1, 25%F2F3, 19%F4. During the 7 years median-follow-up 57% were treated [402 (16%) were SVR, 1006 (41%) non-responders (NR)] and 1077 (43%) non-treated (NT). A total of 157 pts (at 10 years 20.1% [95%CI(15.0-25.3)] died, 109 from LRD (15.2%[10.2-20.3]); 31patients (1.5% [1.0-2.1] at 10 years) have been transplanted; the incidence of first events occurring at least 6 months after FT were: 54 LPC [7.0%(4.0-10.1)] including 43 HCC [6.7%(1.2-10.3), 13 A [1.5(0.4-2.6)] and 2 E (0.1%). Baseline FT and TE had significant and not different performances for OS, S-LT, S-LRD and S-HCC. Only FT had significant performances for predicting the rare occurrence of A and VB (Table).

Conclusion

In pts with CHC, FT and TE had highly significant performances at 10 years for predicting OS, S-LT and HCC. The advantage of FT was the higher reliability rate and a possible higher sensitivity for predicting ascites and variceal bleeding.

Survival endpoint	FibroTest n=2485	TE n=2485	FibroTest vs TE n=2485
"	Risk Ratio (95%CI) P-Value adjusted on treatment, virological response, center, HIV, age and gender		% AUROC P- V alue
Overall	110 (51-239) =.0004	20 (13-31) =.0001	80 (76-83) vs 80 (75-84) =.97
Without transplantation	189 (78-455) =.0001	29 (18-45) =.0001	81 (77-85) vs 80 (76-84) =.57
"	441 (149-1000) =.0001	49 (29-84) =.0001	80 (75-84) vs 81 (76-85) =.23
Without liver complications	146 (71-301) =.0001	1.9 (0.3-12) =0.51	85 (81-89) vs85 (79-89) =.91
"	>500 (276-1000) =.0001	35 (14-89) =.0001	87 (83-91) vs 88 (83-91) =.95
"	>500 (87-1000) =.0002	Cox not applicable	90(84-94) vs 91 (78-97) =0.57
"	>500 (14-1000) =.003	Cox not applicable	84 (60-94) vs 87 (53-97)=0.45

#2231

2013
FibroTest
Cirrhosis

Tue, Nov 05
8:00 AM

FibroTest (FT) performances for the diagnostic and prediction of varices and decompensation in hepatitis C cirrhotic patients

Thierry Poynard et al. APHP UPMC Groupe Hospitalier Pitié-Salpêtrière, Paris, France.

Aim

Garcia-Tsao et al (Hepatology 2010) encouraged moving beyond the characterization of cirrhosis as a single stage and instead thinking of cirrhosis as a series of critical steps that culminate in hepatic decompensation. FT has been validated as a marker of METAVIR fibrosis stages from F0 to F4 using biopsy, methods without gold standard and liver related mortality. The aim of the present study was to validate FT as a marker of compensated cirrhosis (F4) without varices, vs compensated with varices (F5) and vs decompensated (F6) defined by the following events: ascites, variceal hemorrhage (VH), encephalopathy, jaundice and HCC.

Methods

Previously non-responder patients of the EPIC3-F4 randomized trial of maintenance PEG-IFN vs no-treatment (Bruix Gastro 2011) were included in this ancillary study if they had at least one baseline interpretable FT and endoscopy. The FT accuracy for the diagnosis of F5 among cirrhotic patients was assessed transversally using endoscopy at baseline. The FT predictive value for F5 was assessed longitudinally using the occurrence of varices among patients without baseline varices (F4). For F6, occurrences were decompensation predetermined clinical events (ascites, encephalopathy, Child C, variceal bleeding, HCC) adjudicated by an independent committee of experts blinded to treatment and FT.

Results

From the 626 patients with biopsy-confirmed cirrhosis randomized in the trial (RCT), 574 were included in the diagnostic study, 286 Treated by PEG-INTRON and 288 Observed. Characteristics of 574 pts of the diagnostic study were similar to those not-included. At baseline 73 F5 pts (with varices) had higher FT [0.82 (95%CI 0.79- 0.86)] than 501 pts F4 (without varices) [0.77 (95%CI 0.75-0.78);P=0.007]. At 5 years (mean 32 months) FT was significantly associated with occurrence of F6 (clinical events n=61), including HCC (n=24), and occurrence of F5 (varices progression, n=30) (Table). FT predictive values persisted after adjustment (Cox) on treatment randomization for shown endpoints and also for ascites, death/transplantation.

Conclusion

In CHC non-decompensated cirrhotic patients FT is associated with presence of esophageal varices and is predictive of the 5 year occurrence of varices (7% FT>0.85 19% FT>0.95) and decompensation (12% FT>0.85 and 36% FT>0.95).

	Incidence of complications Kaplan-Meier % 5 year (95% CI) Risk Ratio (Cox) =P value		
Baseline FibroTest (n)	Varices	Clinical event	HCC
<=0.74 (191)	2 (0-3) 1= Reference	5 (2-9) 1= Reference	3 (0-5) 1= Reference
>0.74-0.85 (128)	5 (1-9) 3.0 (0.7-12.1) =.12	7 (3-12) 1.3 (0.5-3.3) =.50	2 (0-5) 0.9 (0.2-3.8) =.90
>0.85-0.95 (198)	7 (3-11) 4.4 (1.2-15.5) .02	12 (8-17) 2.4 (1.1-5.1) =.04	4 (1-7) 1.4 (0.4-4.5) =.52
>0.95 (57)	19 (7-31) 11.1 (2.9-42.0) =.0004	36 (22-50) 7.56 (3.48-16.39 =.0001	20 (8-33) 7.8 (2.6-23.5) =.0002

#860

2013
FibroTest
Fibrosis regression
HBV

Sun, Nov 03
8:00 AM

Slow regression of liver fibrosis presumed by repeated biomarkers despite long-term virological response in patients with chronic hepatitis B (CHB)

Thierry Poynard et al. APHP UPMC Groupe Hospitalier Pitié-Salpêtrière, Paris, France.

Background and aim

In CHB treated 5 years (yrs) by tenofovir, regression of fibrosis using paired biopsies, was observed in 51% of patients (pts), including 74% pts with regression of baseline cirrhosis (Marcellin 2012). Fibrosis biomarkers such as FibroTest (FT) have been validated for staging and predicting mortality at five-yr in HBV chronic careers in 2 prospective cohorts (Ngo 2008, de Ledinghen 2013). The aim was to assess retrospectively the 10-yr impact of treatments on the fibrosis progression using repeated FT.

Patients and methods

We pooled the updated individual data of the 2 cohorts. Pts were included if at least 2 FT and viral load (VL) were performed. The last and first FT permitted to estimate the fibrosis regression rate (FRR) and the fibrosis progression rate (FPR) using cumulative hazard rates and to identify the risk factors by Cox model. The main endpoint was the prevalence of cirrhosis (F4) at the end of follow-up (FU) vs baseline prevalence. Fibrosis increase or decrease was defined as change of at least 0.20 in FT, equivalent to 1 METAVIR stage.

Results

A total of 741 pts were included; advanced fibrosis in 41%, 14% F4, men 69%, Caucasian 33%, SubSaharan 39%, Asian 20%; 42 yrs old, HBeAg 19%; CHB in 52% and inactive chronic career 48%; 3% >50g alcohol/day, and 23% BMI >27kg/M2. During the 7 yrs median-follow-up 403 CHB were treated mostly continuously by either lamivudine 31%, adefovir 19%, tenofovir 29%, entecavir 16%, or PEG 5%; 309 (42%) were responders (R) with undetectable or <2000 HBV-DNA, 93 (12%) non-responders (NR) and 339 (46%) NT.

The results were disappointing, without reduction of the net number of F4 and a remaining morbidity (5% HCC) and mortality in R (Table). A net reduction of F4 cases (from 15 to 11) was only observed in the 114 pts treated with tenofovir.

In treated pts (107 stage F2F3 and 55 F4) the independent factors associated with FRR were: treatment by tenofovir [Risk Ratio (RR)= 8.2 (1.01-66) p=0.04], lamivudine [RR=8.2(1.3-65) P=0.05] with 2 adjusting factors: last VL [RR=1.6(1.2-2.8) P=0.0009] and baseline FT [RR=157(26-939) P=0.0001). alcohol consumption, HIV, and metabolic factors were not associated with FRR.

Conclusion

Despite the limitations of such retrospective analyses, the impact of long- term HBV treatment seemed disappointing, as the fibrosis regression was slow and responders still at risk of severe complications (5% HCC).

#1207

2013
FibroTest
Cirrhosis
PBC

Sun, Nov 03
8:00 AM

Non-invasive assessment of liver fibrosis in primary biliary cirrhosis (PBC) patients using transient elastography by Fibroscan, Fibrotest (FT) and liver biopsy as reference method

Mona Munteanu et al. BioPredictive Hepatology Research Unit, Paris, France.

Background. PBC is a rare autoimmune liver disease inducing liver fibrosis and cirrhosis. Liver fibrosis evaluation by liver stiffness measurement (LSM) with Fibroscan was already evaluated in PBC with discrepancy in results between studies (Corpechot 2006, Gomez-Dominguez 2008); one study compared directly FibroTest (FT) with LSM, but only in very few pts. (Friedrich-Rust 2010) Aims. 1) To evaluate the FT diagnostic value for liver fibrosis in PBC patients (pts) by taking liver histology as reference method; 2) To compare directly the performances of FT and LSM for advanced fibrosis and cirrhosis.

Methods. 100 pts with PBC were pre-included retrospectively with LSM, liver biopsy and FT done blindly of clinical data on serum stored at -80°C. Applicability of FT evaluated by an expert system eliminating unreliable scores at calculation; applicability of LSM was defined as the sum of results without failure and unreliable results (<10 valid LSM, success rate <60% and an ratio interquartile range/LSM >30%).

Results.100 PBC pts were pre-included with FT and N=96 included with applicable FT, median age 57yrs(22-89) et BMI 23.8kg/m2(16.8- 33.2). 75/96 pts had liver biopsy before transplantation (N=12) within a median delay of 0 months (0-12.5yrs) and 87/96 had LSM (M-probe) within 0 months (0-6.3yrs) from FT. LSM applicability of was 72.4% significantly lesser than that of FT (96%), p=0.03. Medians (range) size of biopsy samples was 17mm(3-37). Fibrosis prevalences (METAVIR classification) was: 15% F0, 29% F1, 24% F2, 8% F3, 24% F4. Standard AUROCs (95%CI) for FT were: for advanced fibrosis (F2F3F4) 0.75(0.60-0.84), F3F4 0.80(0.64-0.89) and for cirrhosis (F4) 0.88 (0.76-0.94). In N=62 pts with concomitant applicable FT and LSM, the Spearman correlation coefficient was 0.64 (p<0.0001). 45/62 pts had liver biopsy and standard AUROCs (95%CI) for FT and LSM were, respectively: to exclude fibrosis 0.82(0.64-0.91) vs 0.81(0.64-0.91, p=94), F2F3F4 0.78(0.58-0.89) vs 0.90(0.75-0.96, p=0.05), F3F4 0.87(0.72-0.94) vs 0.91(0.68-0.98, p=0.45) and cirrhosis F4 0.91(0.76-0.97) vs 0.95(0.84-0.99, p=0.30). In transplanted pts (N=12), for the diagnosis of F3F4, the concordance between FT and biopsy was 100% (p=0.005) and similar for LSM (N=6 pts, p=0.01).

Conclusion. In retrospectively evaluated PBC pts, serum marker FibroTest and transient elastography by Fibroscan could predict liver fibrosis with high diagnostic value for advanced fibrosis and cirrhosis. In PBC transplanted patients, both FibroTest and transient elastography were highly concordant with histological staging for severe fibrosis and cirrhosis.

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