NAFLD

NashTest 2, a new quantitative blood test, for the assessment of the severity of NASH

Validation of a New Quantitative Blood Test, Nash-Fibrotest-2 (NT-2), for Assessing Nash Severity in a Phase 2 Clinical Trial of Selonsertib

V Peta, S Jayakumar, PS. Mantry, E Lawitz, S Djedjos, M Subramanian, R Myers, AM Diehl, S Caldwell, MR. Charlton, NH. Afdhal, ZD Goodman, T Poynard, R Loomba and GS-US-384-1497 Investigators.
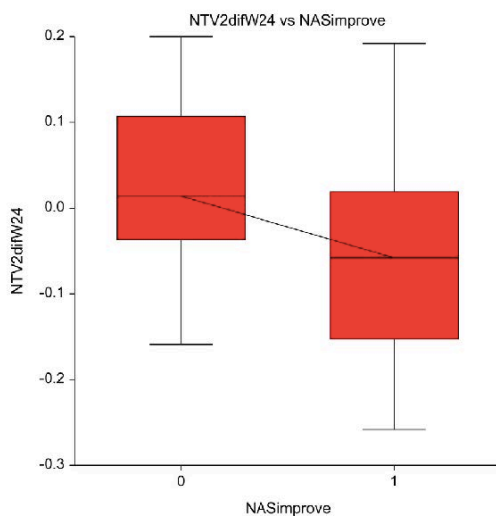
A new blood test, NT-2, was recently derived and internally validated for assessing the severity of nonalcoholic steatohepatitis (NASH) in a large population of patients with NAFLD. (EJGH 2018)

The authors aimed to externally validate NT-2 in NASH patients in a phase 2 trial of selonsertib (SEL).

In this multi-center study, 72 subjects with NASH (NAFLD Activity Score [NAS] ≥5 (100%) and NASH CRN F2 [35%] and F3 [65%] fibrosis) were included with liver biopsies, and serum markers – NashTest 2 (NT-2), FibroTest, and SteatoTest (Biopredictive; Paris, France)- performed at baseline (BL) and W24. For the purpose of this analysis, study groups were combined: those receiveing SEL alone or in combination with simtuzumab (SIM) or SIM alone for 24 weeks (W24). Histological improvement (responders), was defined as ≥1-point improvement in NAS.

At W24, NAS improved in 49% of patients, becoming <3 in 21%; NT-2 was normal (<0.25) in 6% and remained severe (≥0.75) in 51% of patients. The mean improvement (95% CI) in NT-2 was -0.06 (-0.02, -0.11) in responders vs +0.01 worsening (-0.02; 0.05; p=0.006) in non-responders (Figure). Similarly, SteatoTest improved by -0.04 (95% CI -0.08, 0.00; p=0.02) and FibroTest improved by -0.02 (-0.05, 0.01) in responders versus increases of +0.01 (-0.01, 0.04) and +0.03 (0.01, 0.06; p=0.04), respectively, in non-responders. In logistic regression, the association between changes in NT-2 and histologic improvement persisted after adjustment for gender and presence of diabetes.

In conclusion, this external validation cohort from a multi-center clinical trial, changes in NT-2 predicted improvement of NAS in patients with NASH.

POSTER 2295

NAFLD and NASH: Clinical II

Monday, Nov 12 8:00 AM

SteatoTest 2, a new quantitative blood test, for the assessment of the severity of stéatosis

The Diagnostic Performance of a Simplified Blood Test (SteatoTest 2) for the Prediction of Liver Steatosis.

T Poynard, V Peta, M Munteanu, F Charlotte, Y Ngo, A Ngo, H Perazzo, O Deckmyn, R Pais, P Mathurin, R Myers, R Loomba, V Ratziu and FLIP FIBROFRANCE CPAM OBESE Selonsertib Author's Group.

Serum biomarkers of steatosis such as the SteatoTest are recommended for large scale screening studies because imaging is less accessible and more expensive (European EASL-EASD-EASO guidelines 2016).

The primary aim of this study was to construct a new, simplified SteatoTest 2 (patent pending), that was not inferior to the first generation SteatoTest to predict NAS CRN steatosis grades S1-to-S3 versus grade S0 but that did not include body mass index (BMI) or total bilirubin*.

A total of n=2,997 patients from five different subsets previously published, with biopsies and case controls were evaluated, along with four target populations with increasing metabolic risks to assess the prevalence of steatosis: T1 (n=327 blood donors), T2 (n=7,416 healthy volunteers), T3 (n=359 type2-diabetics) and T4 (n=133,045 presumed NAFLD). The performances were assessed using the non-inferiority test (0.10 margin) with the difference between AUROCs to predict NAS CRN steatosis grades 1-to-3 versus grade 0.

Compared to the SteatoTest, SteatoTest 2 did not include weight, height or total bilirubin, but did include transaminases AST, with different coefficients for the remaining 9 components.
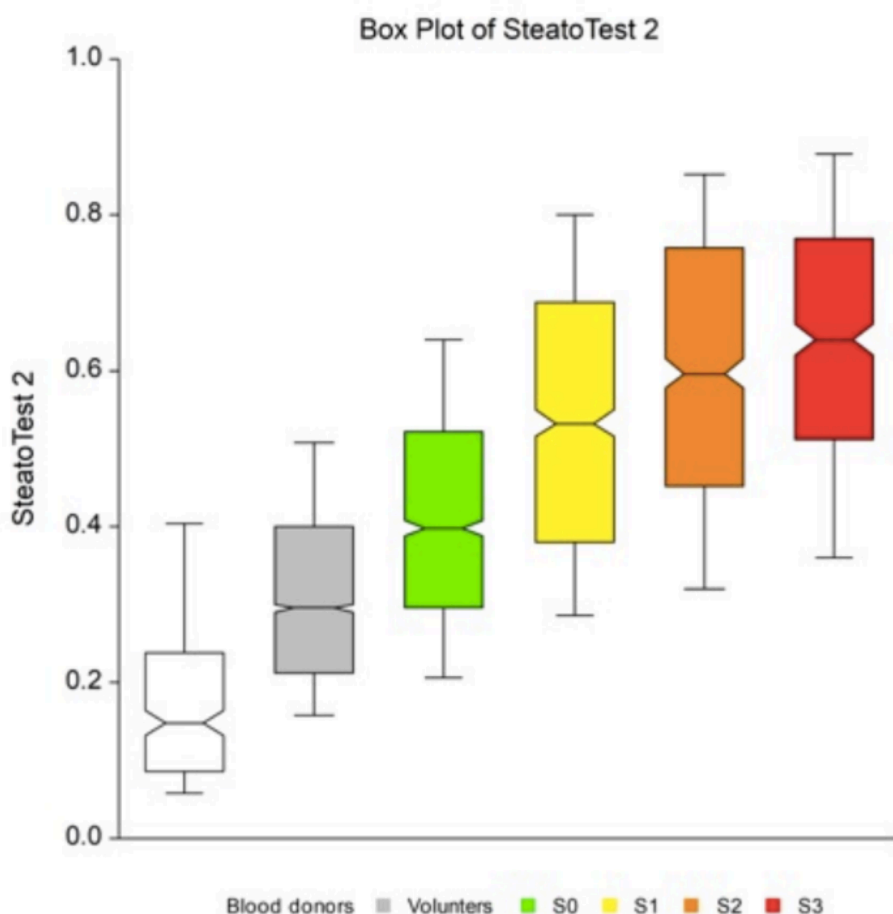
The AUROCs of the SteatoTest 2 were non-inferior to the reference test and all non-inferiority tests were significant ($P<0.001$). AUROCs (95%CI) varied according to subsets and the prevalence of steatosis from 0.772 (0.713-0.820) in 2,997 cases with biopsy (62% prevalence of steatosis) to 0.822 (0.810-0.834) in 5,776 cases (32% prevalence) including controls without risk factors of steatosis.

The SteatoTest-2 medians (IQR) were all significant (Figure) between each group, as the risk of steatosis increased, from blood donors and healthy volunteers populations, to CRN grades of patients with biopsy (all $p<0.001$).

Sensitivity analyses stratified according to glucose cutoffs (6.1 or 7.0 mmol/L) as well as for BMI≥30 kg/m2 found similar prevalences of steatosis in these risk subgroups.

In conclusion, the new multi-analyte SteatoTest-2 is simpler than the first SteatoTest, and has been shown to be non-inferior for the diagnosis of steatosis, with no limitation due to the variability of the body mass index and the risk of false positives from unconjugated bilirubin

*BMI and bilirubin are two components that could increase the variability in the assessment of weight and height, and in case of Gilbert syndrome or hemolysis, respectively.

Box Plot of SteatoTest 2

Blood donors ▫ Volunters ▪ S0 ▪ S1 ▪ S2 ▪ S3

Screening Type 2 Diabetic patients using FibroTest, SteatoTest and the quantitative NashTest-2

Factors Affecting Hepatic Steatosis (HS) in Patients with Diabetes Melitus Type 2 (DM)

A Meritsi, A Thanopoulou, M Noutsou, E Tsitsopoulos, P Koussis, H Moschogianni, P Zoumpoulis, S Manolakopoulos, SP Dourakis and EK Manesis.

Authors aimed to assess individual factors affecting the degree of steatosis in patients with type 2 diabetes (T2D) patients.

Steatosis was assessed by MRI-PDFF, SteatoTest (FibroMaxTM panel). NashTest evaluated the steatohepatitis severity along with FibroTest (FibroMaxTM panel) for the fibrosis severity also quantified by unidimensional liver stiffness (LS, kPa) and 2D-shear wave elastography (2D-SWE). PNPLA3 gene polymorphism was tested and the total body fat (TBF) was calculated.

A total of n=100 T2D (63% males, age 60.2±8.5 years, T2D duration 10.3±7.6 years, PNPLA3 polymorphism GG 8.5%). In univariate analysis, steatosis was positively correlated with SteatoTest (r2 0.323, p<0.0001), NashTest (r2 0.289, p<0.0001) and also with triglycerides, BMI, T2D duration, waist circumference (all p<0.05) and negatively correlated with age (r2 -0.264, p<0.001). In multivariate analysis, the percentage of steatosis, as measured by MRI-PDFF, increased by 2.1 (p=0.015) in the presence of PNPLA3 mutations; by 9.5 (p<0.001) for each log10 increase of serum ALT; by 13.5 (p<0.01) for each log10 increase of LS; by 10.8 (p=0.001) for each log10 increase of NashTest and decreased by 2.1 for each increasing decade of age.

In conclusion, in T2D patients, steatosis is more important in the presence of PNPLA3 gene polymorphism, increased inflammatory activity (NashTest and ALT) and increased LS. Steatosis decreased with age.

FibroTest correlates with plasma lumican a surrogate of hepatic collagen synthesis in NASH

Validation of Fractional Synthesis Rate of Plasma Lumican As a Noninvasive Marker of Fibrogenesis in Patients with Nonalcoholic Steatohepatitis (NASH)

R Loomba, E Lawitz, EJ Gane, PJ Ruane, J Zhang, L Wang, G Chen, BJ McColgan, C Chung, M Subramanian, R Myers, MS Middleton, M Noureddin, SA Harrison, KW Li and M Hellerstein.

The sudy describes the longitudinal associations between the fractional synthesis rate of plasma lumican (FSRLUM,%/day), a surrogate of hepatic collagen synthesis, and markers of fibrosis in subjects with NASH and F2-F4 fibrosis receiving ASK1 inhibitor selonsertib, ACC inhibitor GS-0976, and/or the FXR agonist GS-9674, alone or in combination, orally QD for 12 weeks.

Associations between FSRLUM and fibrosis markers at baseline and changes over 12 weeks were evaluated.

At baseline, FSRLUM correlated with fibrosis markers including FibroTest, MRE-stiffness, ELF, TIMP-1, hyaluronic acid, and APRI (Spearman ρ=0.22-0.37; all p<0.05; Table).

Subjects with high baseline FSRLUM (≥4%/day) had also significantly higher FibroTest, MRE-stiffness, GGT, and CK-18 M65 compared with subjects with low baseline FSRLUM (Table).

Authors concluded that in patients with NASH, FSRLUM correlates with fibrosis markers at baseline, including FibroTest, and for changes over time, suggesting that those with active fibrogenesis may be more likely to have anti-fibrotic benefit with these therapies.

Table: Associations between FSR$_{LUM}$ and other Noninvasive Markers at Baseline

Assessment		Correlation with BL FSR$_{LUM}$ (p-value)	BL FSR$_{LUM}$ ≥4%/day (n=41)	BL FSR$_{LUM}$ <4%/day (n=54)
Imaging	MRE-stiffness	0.37 (p<0.001)	4.01 (3.37, 5.05)*	3.44 (3.09, 3.93)*
	MRI-PDFF	-0.04 (p=0.733)	16.51 (11.66, 20.94)	16.21 (12.31, 20.14)
Liver Biochemistry	ALT	0.11 (p=0.270)	54 (35, 95)	49.5 (36, 76)
	AST	0.19 (p=0.069)	46 (32, 75)	42.5 (29, 60)
	GGT	0.41 (p<0.001)	63 (48, 111)*	50 (31, 77)*
	Total bilirubin	0.20 (p=0.048)	0.5 (0.4, 0.7)	0.4 (0.3, 0.5)
Serum Markers of Fibrosis and Apoptosis	ELF	0.24 (p=0.020)	9.73 (9.28, 10.76)	9.67 (9, 10.39)
	Hyaluronic acid	0.22 (p=0.031)	64.84 (44.37, 136.77)	55.64 (27.22, 94.94)
	TIMP-1	0.23 (p=0.028)	269.6 (235.6, 347.2)	263.5 (220.2, 301.3)
	PIII-NP	0.19 (p=0.068)	11.57 (8.71, 14.34)	9.96 (7.64, 12.65)
	FibroTest	0.22 (p=0.035)	0.34 (0.21, 0.52)*	0.26 (0.15, 0.41)*
	APRI	0.24 (p=0.021)	0.82 (0.45, 1.18)	0.57 (0.33, 0.94)
	CK18 M65	0.24 (p=0.020)	660 (343, 1361)*	444.5 (193, 736)*

Continuous data are median (IQR).
* p<0.05 for comparison between BL FSR$_{LUM}$ ≥4%/day vs. <4%/day.

FibroTest recommended by EASL clinical practice guidelines in patients with NAFLD risk

Testing Easl Clinical Practice Guidelines Recommendations for Specialist Referral of NAFLD Patients with Real-Life Data

B Kutala, R Pais, F Charlotte, P Lebray, D Thabut Damais and V Ratziu

The authors proposed to test with real-life data the performance of the algorithm by multistep approach based on steatosis on imaging, aminotrasferases (AT>30IU/L) and serum fibrosis markers FibroTest, FIB4 and NAFLD –Fibrosis Score (NFS) recommended by the current EASL clinical practice guidelines (CPG, J Hepatol 2016) in patients with metabolic risk factors (MRF).

565 pts with MRF that underwent liver biopsy (LB) were stratified as recommended by CPG [mean age 53 yrs, 59% males, mean BMI 31kg/m², 45% diabetes, 58% NASH and 26% F3/4]. Groupe A (n=159) had normal AT with steatosis; Group B (n=26) had normal AT without steatosis; and Goup C (n=380) increased AT regardless of steatosis.

CPG does not recommend LB in Group A-low fibrosis risk and Group B pts. It recommends specialist referral for biopsy in Groups C and A-high fibrosis risk. The histological outcomes were: % of NASH to be treated, as defined by FDA (NAS≥4 and Fibrosis F2-4) and % of advanced fibrosis (F3/4), that would have been missed in Group A-low fibrosis markers risk and Group B.

Among pts with normal AT, the % of F3/4 in Group B (without steatosis) was 2% and in Group A-low risk (with steatosis) 10% with FibroTest and 12 and 12.5% with FIB4 and NFS, respectively.

The prevalence of NASH was 0% in Group B but unacceptably high in Group A-low risk: 54% with FibroTest and FIB4 and 50% with NFS. Combining fibrosis markers for low risk definition further reduced the prevalence of missed F3/4 to 0% with best combination FibroTest-NFS but not the % of missed NASH (higher than 45% with all combinations) that was significantly improved only by age threshold of 45 years.

Authors concluded that the EASL CPG with current serum fibrosis markers, are performant for excluding advanced fibrosis in patients with MRF and suspected NAFLD but would miss too many patients qualifying for pharmacotherapy, particularly among pts with steatosis, older than 45 and normal AT. Therefore, age should be accounted for in the CPG algorithm.

Antifibrotic trial

FibroTest in a longitudinal trial for the assessment of liver antifibrotic oral drug efficacy

Pirfenidone in Combination with Standard of Care in Patients with Advanced Liver Fibrosis. Open Trial Focused on Safety, Fibrosis Efficacy, and Pharmacokinetic Data.

J Poo, LE Munoz-Espinosa, T Aldo, M Cruz, L Mejía-Cuán, Dr. EC Reyes, A Velazquez, I Arellano, A Patiño, FJ Bosques, L Hernández, F Gasca, F Flores-Murrieta, S Treviño and JR Aguilar Ramirez

Authors have proposed to assess a new drug, Pirfenidone (PFD)* (600 mg bid, for 12 months), on liver fibrosis progression using 2 non-invasive methods: FibroTest and transient elastography (TE) in n=84 patients receiving PFD from 11 centers.

Variations ≥0.10 units in FibroTest and ≥5 kPa or 1 point in METAVIR staging, were considered as significant. Baseline fibrosis was 74% F4 and 26% F3, 58% were women, mean age 64 yrs, 44% NAFLD, 22% viral hepatitis, 17% autoimmune, 17% alcohol. Mean biochemical values remained stable between M0 and M12. In relation to fibrosis progression, authors detected three different outcomes: progressive (6%), stable (61%) and regressive (33%), the last ones having plasma PFD levels significantly higher compared to two other groups. TGFβ1 levels were lower after treatment compared to baseline values. 18% reported side effects (burning or nausea, and 7% photosensitivity. Six patients did not complete 12 months of treatment and progressed to mortality, 3 due to liver disease and 3 non-liver related. Quality of life scale improved from 62 ± 5 to 84 ± 3 (p < 0.001), and FACIT scale from 32 ± 3 to 42 ± 2 (p <0.008).

Conclusion: Pirfenidone was well tolerated by patients with advanced liver fibrosis and appears to be associated with promising antifibrotic effects deserving further evaluation.

* Oral antifibrotic drug for the treatment of idiopathic pulmonary fibrosis (EMA and FDA aprroved)

FibroTest significant improvement with AgHBe loss during NUC therapy (TAF or TDF)

Loss of Hepatitis B e Antigen (HBeAg) during Nucleos(t)Ide (NUC) Therapy Is Associated with Greater Improvement in Liver Fibrosis

M Buti, SK Fung, SH Ahn, GR Foster, JC Yang, H Wang, JF Flaherty, A Gaggar, M Subramanian, KS Byun, CY Peng and P Marcellin

The aim of this investigation was to evaluate the effects of HBeAg loss during long-term NUC therapy on liver fibrosis regression estimated by FibroTest in a viremic HBeAg+ chronic hepatitis B population (CHB) from an ongoing Phase 3 study [GS-US-320-0110, TAF or TDF once daily for up to 8 years].

FibroTest scores were generated at BSL and every 48 weeks (WKs). FibroTest categories (Metavir fibrosis scores) were: <0.49 (F0-F1), 0.49 to <0.75 (F2-F3), and ≥0.75 (F4). ALT normal levels defined as <19 U/L female and <30 U/L male.

N= 770 HBeAg+ patients (Asian 82%, male 65%, and NUC-naïve 74%) were randomized to TAF (n=517) and to TDF (n=253). Rates of HBeAg loss at WKs 48, 96 and 144 were: 106 (14%), 174 (23%), and 193 (27%), respectively and were similar by treatment, TAF or TDF, by WK 96. A higher rate of ALT normalization by WK 96 was observed in patients with vs without HBeAg loss with a higher rate observed in TAF vs TDF treated patients by WK 96.

Key BSL characteristics and change from BSL in FibroTest are presented by HBeAg status at WK 96 in the Table. Mean decline from BSL in FibroTest was observed in patients with and without HBeAg loss; however, HBeAg loss patients had a greater decline in FibroTest scores at WK 144 (Table).

Patients with HBeAg loss by WK 96 were more likely to have FibroTest ≥0.75 (13% vs 6% in HBeAg+) at BSL and were older, non-obese, had lower HBV DNA and higher ALT levels. A higher proportion of patients with vs without HBeAg loss had ≥1 stage categorical improvement in FibroTest: 21% vs 10%, 17% vs 10%, and 16% vs 9%, at WKs 48, 96, and 144, respectively.

Authors concluded that improvement in liver fibrosis by FibroTest was observed in CHB patients during NUC therapy regardless of HBeAg status. However, patients with HBeAg loss by Week 96 had a greater improvement in FibroTest scores then those that remained HBeAg+ suggesting a possible role for HBeAg loss in reducing fibrogenesis.

Table	HBeAg Loss at Week 96 (N=174)	HBeAg+ at Week 96 (N=596)	P-Value
Baseline Characteristics			
Age, mean (SD)	40 (11)	38 (11)	0.04
BMI ≥30 kg/m², n (%)	2 (1)	48 (8)	<0.01
Presence of Cirrhosis, n (%)	16 (13)	38 (9)	0.15
HBV DNA (Log $_{10}$ IU/mL), mean (SD)	7.4 (1.3)	7.7 (1.3)	<0.01
ALT (U/L), mean (SD)	144 (137)	111 (96)	<0.01
Mean (SD) FibroTest Score			
Absolute Baseline FT Score	0.39 (0.24)	0.32 (0.2)	<0.01
Change at Week 48	-0.09 (0.14)	-0.05 (0.12)	<0.01
Change at Week 96	-0.07 (0.15)	-0.04 (0.13)	<0.01
Change at Week 144	-0.07 (0.17)	-0.04 (0.13)	0.01

FibroTest predicts outcomes and death in excessive alcohol drinkers

Non-Invasive Markers Are Superior to Histological Fibrosis Stage for Predicting Liver-Related Outcomes in Alcoholic Liver Disease

D Rasmussen, M Thiele, B Stæhr Madsen, L Møller, S Antonsen, S Detlevsen and A Krag

This prospective study in adults with a history of excess drinking for at least 5 years and without decompensated cirrhosis aimed to make a head-to-head comparison of the prognostic performance between validated tests for liver fibrosis: FibroTest, the Enhanced Liver Fibrosis test (ELF), transient (TE, FibroScan) and 2-dimensional shear-wave elastography (2D-SWE, Aixplorer), compared to histological Kleiner fibrosis stage (all performed on the same day).

Hepatic events were defined as development of alcoholic hepatitis, varices needing treatment, variceal bleeding, ascites, spontaneous bacterial peritonitis, hepatic encephalopathy, and hepatocellular carcinoma or hepatorenal syndrome. Fibrosis stages F0-1, F2 and F3-4 were defined using validated cut-offs: FibroTest <0.31, 0.31-0.58 and ≥0.58; ELF <9.8, 9.8-10.5 and ≥10.5; TE <10kPa, 10-15kPa and ≥15kPa, 2D-SWE <10kPa, 10-16.4kPa and ≥16.4kPa.

N=250 patients [median age 56 years, 72% males, 25% F3F4 stages] were included with a median follow-up 32 months (range 18-51). Among them, 11% died and 20% had a hepatic event.

For the survivals without hepatic event: TE, 2D-SWE, ELF, FibroTest and fibrosis stage predicted hepatic outcomes with a Harrell's C of 0.86, 0.85, 0.84, 0.80 and 0.79, respectively. The hazard ratios for a hepatic event after controlling for fibrosis stage are presented in Table.

For the survivals without death: ELF, TE, 2D-SWE, FibroTest and fibrosis stage predicted death with Harrell's C at 0.80, 0.78, 0.75, 0.74 and 0.73, respectively.

Authors concluded that non-invasive markers of fibrosis predict liver-related outcomes and death with high accuracy in alcoholic liver disease. The strengths of the study are the methodology and the use of direct comparisions between markers. However, several limitations should be highlighted related to the small number of events, the short median follow up and the absence of data about applicability of elastographic methods.

Hazard ratios of non-invasive from multivariable Cox regression controlling for fibrosis stages F0-1, F2 and F3-4			
	Group	HR (CI)	P-value
TE	10-15 kPa	13.10 (2.84-60.31)	0.001
	≥15 kPa	33.08 (7.22-15.49)	0.001
2D-SWE	10-16.4 kPa	5.12 (1.52-17.23)	0.008
	≥16.4 kPa	7.42 (2.38-23.18)	0.001
ELF	9.8-10.5	1.62 (0.40-6.64)	0.500
	≥10.5	8.80 (3.15-24.58)	0.000
Fibrotest	0.31-0.58	4.03 (1.37-11.81)	0.011
	≥0.58	4.28 (1.48-12.37)	0.007

FibroTest in HCV trials for the screening of cirrhosis

Sofosbuvir/Velpatasvir for Patients with Chronic Genotype 3 HCV Infection with Compensated Cirrhosis: An Integrated Analysis of Phase 2 and Phase 3 Clinical Trials

SK Roberts, M Buti, GR Foster, JL Calleja, A Sood, VA Isakov, R Ola, H Weiland, L Stamm, L Ni, E Svarovskaia, D Brainard, DL Wyles, JA Pineda, A Thompson, R Esteban-Mur and A Mangia

This retrospective analysis in multiple Phase 2 and Phase 3 clinical trials (Table) including with genotype 3 HCV and compensated cirrhosis, aimed to assess the pangenotypic fixed-dose combination of sofosbuvir and velpatasvir (SOF/VEL) for 12 weeks.

N=337 patients were enrolled at 147 sites in 11 countries [mean age (range) was 53 years (21-76), 73% were male, 31% were treatment experienced and 6% had HCV/HIV coinfection].

Cirrhosis was determined at screening by the combination of FibroTest >0.75 and APRI > 2 or transient elastography (TE) >12.5 kPa. Baseline median (IQR) FibroTest score was 0.79 (0.63, 0.89) and TE score was 18 kPa (14-26). The overall sustained viral response at 12 weeks (SVR12) rate was 94% with a relapse rate of 4%. (Table)

Results in patients enrolled in Phase 2 and Phase 3 trials demonstrated the efficacy SOF/VEL for 12 weeks for patients with genotype 3 and compensated cirrhosis as per FibroTest or TE and APRI.

	Phase 2	Phase 3					Total
	GS-US-342-2097 (Spain)	GS-US-342-1140 (ASTRAL-3)	GS-US-367-1173 (POLARIS-3)	GS-US-342-1202 (ASTRAL-5)	GS-US-342-1521 (India)	GS-US-342-1522 (Russia and Sweden)	
SVR12	91% (92/101)	91% (73/80)	96% (105/109)	100% (3/3)	97% (32/33)	100% (11/11)	94% (316/337)
Relapse	5% (5/99)	9% (7/80)	1% (1/107)	0% (0/3)	3% (1/32)	0% (0/11)	4% (14/332)

FibroTest for the evaluation of fibrosis in prison inmates before short DAA regimens

Excellent Completion RATE of Short Hepatitis C Treatment in Prison; Results of French National Study.

AJ Remy, JM Ruiz, A Baron, P Alarcon, C Goubin, JC Guichard

The present prospective non-interventional multicenter trial among prison inmates from 6 French prison units aimed to evaluate the completion rate and the effectiveness of an 8-week antiviral C treatment by sofosbuvir/ledipasvir (SOF/LEDI) regimen in non-cirrhotic genotype 1 patients with METAVIR fibrosis score F0-F2.

Fibrosis has been evaluated by FibroTest and/or transient elastography (TE).

N=115 patients were included (81% men, mean age 41 years, 74% genotype 1a, 9% F2 METAVIR stage). Mean FibroTest was 0.21 (n=37) and mean TE 3.5kPa (n=89).

Authors observed a completion rate of 94% for included patients with 8 weeks SOF/LEDI regimen and concluded on the efficiency of short treatment in prisoners.

NUMBER: 0628

Hepatitis C Therapeutics: Approved Agents

Friday, Nov 9 8:00 AM

NUMBER: 0647

Hepatitis C Therapeutics: Approved Agents

Friday, Nov 9 8:00 AM

FibroTest for disease staging in a test and treat model

Time to Progression through the Hepatitis C Care Continuum in a Federally Qualified Health Center

L Magaldi, J Anderson, N Brown, CR Coleman, J Evans, J Kostman, TWL Preston, A Ripkin, R Rivera and S Trooskin

Authors aimed to describe the time lapsed to move through the HCV care cascade prior to the removal of treatment restrictions for persons tested in community or clinic settings and treated in a Federally Qualified Health Center (FQHC) in the United States.

"Disease staging" (DS) was defined as per either a FibroTest (Fibrosure) or transient elastography (TE) and "engagement in HCV care" (eHCV-care) as attending three appointments within the FQHC.

N=1015 HCV adults were included, 63% from community sites and 37% from clinic setting and 73% (n=732) were found to be HCV RNA positive.

Those tested in the community versus clinic setting waited a mean of 51 vs 3.5 days for a first appointment, 77 vs 20 days for disease staging, 117 vs 101 days for HCV care engagement and 140 vs 151 days to start medication.

Authors concluded that those patients tested in the community waited longer for a first appointment with a subspecialist and for disease staging by noninvasive methods. Expansion of navigation services to all chronically HCV infected patients, may be required to optimize a test and treat model for HCV elimination.

	total # subjects	mean # of days to event	clinical # of subjects	mean # of days to event	community # of subjects	mean # of days to event	p-value
ab+ to linked	387	20.03	241	3.49	146	51.19	p=0.11
ab+ to staged	330	31.72	209	19.93	121	76.78	p<0.0001
ab+ to engaged	246	105.41	170	101.36	76	117.46	p=0.27
ab+ to start meds	207	147.75	135	151.13	72	139.71	p=0.33
ab+ to end meds	139	219.21	102	219.84	37	213.58	p=0.43
ab+ to SVR12 draw	60	311.58	48	314.1	12	300.55	p=0.33