Comparison of the prevalence of advanced fibrosis (AF) using two combinations Liver stiffness measurement (LSM or VCTE Fibroscan) along with LiverSTAT (LST) or FIB-4 in a prospective chronic liver diseases (CLD) cohort

#41

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BACKGROUND

Sequential pathways using noninvasive tests (NITs), FIB-4 followed by Liver Stiffness Measurement (LSM) have been developed to identify advanced fibrosis in main chronic liver diseases. LiverSTAT, a blood-based AI-algorithm combining seven biochemistry assays with anthropometrics, outperformed FIB-4 in metabolic dysfunction-associated steatotic liver disease (MASLD) subjects and achieved 86% histological confirmation along with LSM for AF.

(Leow, J Gastroenterol Hepatol. 2024 , DeLédinghen, J Hepatol 2023, Alkhouri, NASH-Tag 2024)

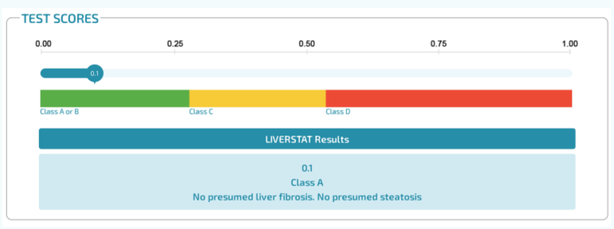
AIMS

Comparative assessments of the prevalence of advanced fibrosis (F3F4) using one-step combination LiverSTAT & LSM versus FIB-4 & LSM in a miscellaneous cohort with chronic liver diseases.

METHODS

LIVERSTAT (Fibronostics, Florida, US)

- AI computer aided proprietary algorithm for assessing fibrosis and steatosis
- Combines seven blood biomarkers and anthropometrics to generate a category of fibrosis/steatosis
- Generates a four categories report: Class D- presumed advanced fibrosis



Class	Interpretation
Class A	No presumed liver fibrosis. No presumed steatosis.
Class B	No presumed liver fibrosis. Presumed steatosis.
Class C	Presumed liver fibrosis, mild or moderate.
Class D	Presumed liver fibrosis, advanced (severe).

FIB-4

- Algorithm: platelet count, age, AST and ALT
- Dual cut-off for advanced fibrosis (<1.3, >2.67)
- Over/underestimation factors: age, cytolysis, T2D
- Lower diagnostic performance for cirrhosis in T2D

$$\text{FIB-4} = \frac{\text{age(years)} \times \text{AS(IU/L)}}{\text{Platelet count } (10^9/\text{L}) \times \text{ALT(IU/L)}^{\frac{1}{2}}}$$

Fibroscan (Echosens, paris, France)

- TE quality criteria: IQR/median<30%, Success rate≥60%, 10 valid LSM
- FibroScan has shown variability in 531 NAFLD (MASLD) patients with paired measurements: one stage difference in 32%, two stages difference in 10%.
- Overestimation of TE: Cytolysis with ALT > 3x ULN, non fasting, MetS: T2D, BMI>30, high blood pressure

- Retrospective analysis on data collected in CLD cohort at the Liver Center, a center-of-excellence for diagnosis, treatment, and research of liver diseases in Mongolia.
- Subjects aged 18 or older without missing data and applicable LSM have been included.
- Subjects were assigned to AF (F3F4) using the following cutoffs in MASLD and CHB/CHC, respectively: for LiverSTAT 0.59 and 0.49; for LSM 12 kPa and 8 kPa; and for FIB-4 2.68 and 1.3 to rule in/out AF.
- The prevalence of AF has been estimated by the agreement between NITs.

RESULTS

Characteristics of Patients (n=745)	
Number of included subjects	n=745
Age (years), median	46 yrs
Gender Male	340 (46%)
Etiology CHB/ HDV superinfection CHC /HCV-RNA+ MASLD	524 (71%)/191 146 (19%)/ 108 72 (10%)
BMI[1] (kg/m^2)	27.6
Diabetes	5.3%
Liver Stiffness Measurement (LSM) , KPa	6.5 kPa
CAP (Fibroscan),dB/m	232 (2)
FIB-4	1.1 (0.1)
ALT, U/L	39 (2)
AST, IU/L	30 (2)

Strength of concordance between LSM (Fibroscan) and LiverSTAT for F3F4

N=745	LiverSTAT Presumed advanced fibrosis (Class D)
LSM Presumed F3F4, ≥12KPa	**44 (5.9%)**
LSM No Presumed F3F4, <12KPa	17 (2.3%)
Total	**61 (8.2%)**

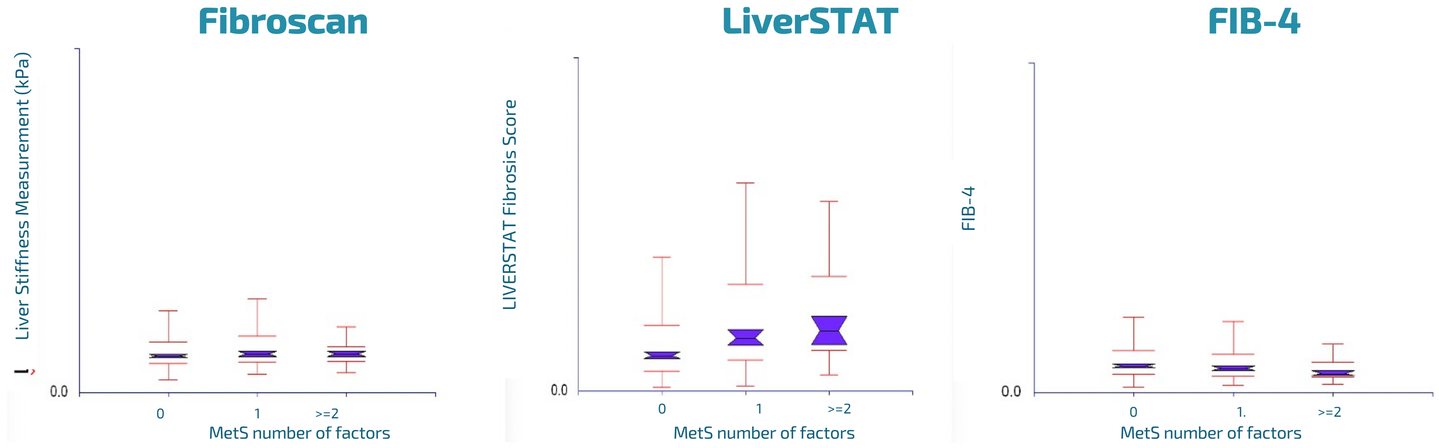
Strength of concordance between LSM (Fibroscan) and FIB-4 for F3F4

N=745	FIB-4 Presumed advanced fibrosis (≥2.68)	FIB-4 1.3-2.67 (indeterminate zone)
LSM Presumed F3F4, ≥12KPa ***LiverSTAT Presumed F3F4 (% from the patients with LSM≥12 kPa***	**57 (7.7%)** ***30/57 (52.6%) confirmed by LiverSTAT***	114 (15.1%) missed cases by FIB-4 ***13/114 (11.4%) identified by LiverSTAT in the grey zone of FIB-4***
LSM No Presumed F3F4, <12KPa	17 (2.2%)	93 (12.8%)
Total	74 (9.9%)	207 (27.9%)

LiverSTAT score was the only NIT correlated to the number of metabolic factors

169 subjects had at least one metabolic syndrome (MetS) factors, independently of the etiology of CLD.

- **LiverSTAT** score increased, as expected, with the cumulative number of MetS factors;
- **LSM** presented no significant increases in scores accordingly to the number of MetS factors and,
- **FIB-4** score paradoxically decreased with the number of MetS factors.



CONCLUSIONS

- In a miscellaneous chronic liver diseases cohort, using the strength of concordance between two non-invasive tests, the prevalence of presumed advanced fibrosis, F3F4, was estimated between 5.9% and 7.7% as per LiverSTAT or FIB-4 in combination with LSM by Fibroscan, respectively.
- Among subjects having at least one metabolic-risk factor, LiverSTAT severity seems to be the most correlated with the MetS-associated risk for liver fibrosis.

FIBRONOSTICS