Comparison of two non-invasive models for the detection of presumed advanced fibrosis (pAF) in patients (pts) with type 2 diabetes (T2D) and MASLD using LiverSTAT (LSTAT) and FIB-4 in combination with liver stiffness measurement (LSM) by Fibroscan

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BACKGROUND

AI-based blood tests LIVERSTAT for advanced fibrosis (AF) in patients with T2D can streamline the diagnostic process.

AIMS

To retrospectively evaluate two combinations, LIVERSTAT & Liver Stiffness measurement (LSM) and FIB-4 & LSM, in identifying presumed advanced fibrosis among pts with T2D and MASLD.

METHODS

Retrospective cohort with T2D and MASLD attending the diabetes clinics at a tertiary university hospital. We used logistic regression to identify independent predictors of pAF presumed with LSM ≥12kPa, FIB-4>2.67 (AASLD-CPG), and LSTAT≥0.59.

- In this retrospective study, we reviewed patients diagnosed with T2D and MASLD with various demographic and clinical factors attending the diabetes clinics at a tertiary university hospital.
- Cut-offs for advanced fibrosis were those recommended by AASLD clinical practice guidelines:
  - ✓ **LSM:** 12kPa (to rule-in F3-F4)
  - ✓ **FIB-4:** 1.3 and 2.67 to rule out/rule in F3F4; and
  - ✓ **LiverSTAT** used a cut-off of 0.59.
- We used logistic regression to identify predictors of advanced fibrosis.

LIVERSTAT (Fibronostics, Florida, US)

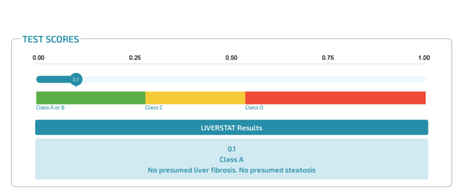
- AI computer aided proprietary algorithm for assessing fibrosis and steatosis
- Combines seven blood biomarkers and anthropometrics to generate a category of fibrosis/steatosis
- Generates a four categories report: Class D- presumed advanced fibrosis

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

•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



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).

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

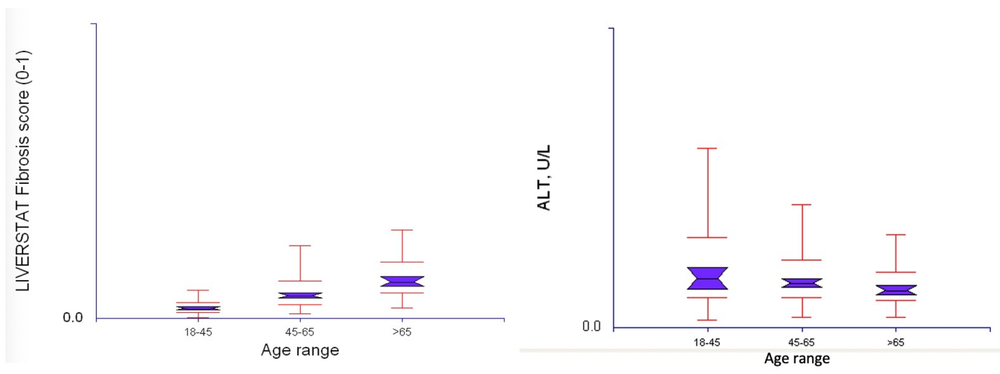
RESULTS

We identified 359 T2D patients; 349 were included with applicable LSM and complete biomarkers

T2D Patients , Tertiary Center Cohort N=359 → **Included** subjects liver assessment with LSM, FIB-4, and LiverSTAT N=349

Excluded (Incomplete data or not applicable LSM by TE) N=10

Fibrosis presumed with LiverSTAT Fibrosis score increases significantly with age while ALT enzymatic activity decreases with the age range in T2D patients



In a model including LiverSTAT biomarkers, FIB-4, platelets, lipid panel, liver enzymes, glucose, age, and BMI, **only age and LiverSTAT** were **independent predictors of advanced fibrosis.**

Characteristics of Patients with T2D (n=349)

Variables	n=349
Age (years), median	55 yrs
Gender Male	46.7%
BMI[1] (kg/m^2)	32.3
Liver Stiffness Measurement, KPa	5.6kPa
CAP (Fibroscan),dB/m	11 (39.3%)
ALT, IU/L	28
ALT < 50 IU/L	273 (78%)
AST, IU/L	21
AST < 50 IU/L	316 (90.5%)
FIB-4	0.87

Strength of concordance between LSM (Fibroscan) and LiverSTAT for the detection of advanced fibrosis
309 (88.5%) had LSM and LiverSTAT that agreed:

N=349	LiverSTAT Presumed advanced fibrosis (Class D)	LiverSTAT No Presumed advanced fibrosis (Class A,B or C)
LSM Presumed advanced fibrosis (F3F4), 12KPa	**23 (6.6%)**	24 (6.9%)
LSM No Presumed advanced fibrosis, <12KPa	16 (4.6%)	**286 (81.9%)**

Strength of concordance between LSM (Fibroscan) and FIB-4 for the detection of advanced fibrosis
254 (72.8%) had LSM and FIB-4 that agreed:

N=349	FIB-4 Presumed advanced fibrosis (≥2.68)	FIB-4 No Presumed advanced fibrosis (<1.3)	FIB-4 1.3-2.67 (indeterminate zone)
LSM Presumed advanced fibrosis (F3F4),≥12KPa	**12 (3.4%)**	18 (5.2%)	53 (15.2%)
LSM No Presumed advanced fibrosis, <12KPa	7 (2.0%)	**172 (69.3%)**	17 (4.9%)

- Among 70 (20.1%) patients with indeterminate FIB-4 results, advanced fibrosis was presumed with LiverSTAT in 19 patients and with LSM in 17 patients.
- In 11 (15.7%) patients, LiverSTAT and LSM agreed on AF, and in 45 (64.3%) patients, they agreed on non-AF.

CONCLUSIONS

- In patients with T2D, LiverSTAT outperformed FIB-4 when combined with LSM for the detection of MASLD-related advanced fibrosis.
- Liver-specific biomarkers should be used instead of liver enzymes, as ALT lacks sensitivity for advanced fibrosis detection, especially in older patients.

FIBRONOSTICS