Association Comparison of two non-invasive models for advanced fibrosis (AF) detection in patients with type 2 diabetes (T2D) and MASLD using LiverSTAT, FIB-4 and liver stiffness measurement (LSM) with transient elastography (TE)

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INTRODUCTION

- Metabolic dysfunction-associated liver disease (MASLD) affects 24% of the population and can progress undetected from simple steatosis to advanced fibrosis (AF) and cirrhosis, especially in patients with type 2 diabetes (T2D). This underscores the importance of early detection and hepatology referrals, as patients with AF are identified late.
- Given the limitations of liver biopsy and the scarce availability of TE, there is a growing need for non-invasive, cost-effective blood-based tests for liver fibrosis assessment. Clinical care pathways integrating AI-based blood tests like LiverSTAT (LST) offer a promising approach to identifying AF in pts with T2D.
- These pathways can streamline the diagnostic process, facilitating early detection and intervention.

AIMS

This study evaluated the efficacy of using LST and LSM in identifying advanced fibrosis among patients with T2D and MASLD comparatively to FIB-4 and LSM.

METHODS

- 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 F3F4) and
  - FIB-4 1.3 and 2.67 to rule out/rule in F3F4;
  - LiverSTAT used a cut-off of 0.59.
- We used logistic regression to identify predictors of advanced fibrosis.

LIVERSTAT (Fibronostics, Florida, US)

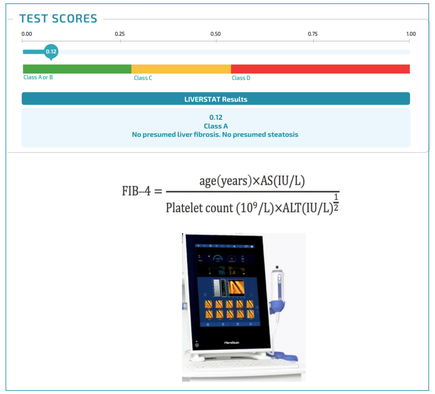
- AI computer aided proprietary algorithm for assessing fibrosis and steatosis
- Combines seven blood biomarkers and anthropometrics to generate a category of fibrosis/steatosis
- Generates a four categories report: Class D- presumed advanced fibrosis

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)

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



We identified 359 T2D pts, 349 pts were included with applicable LSM and complete biomarkers

T2D Patients , Tertiary Center Cohort N=359

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

Included subjects liver assessment with LSM, FIB-4 and LiverSTAT N=349

Characteristics of 349 Included T2D Patients	
Variables	**n=249**
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

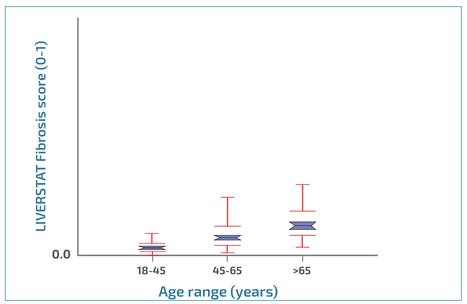
254 (72.8%) had LSM and FIB-4 that agreed:

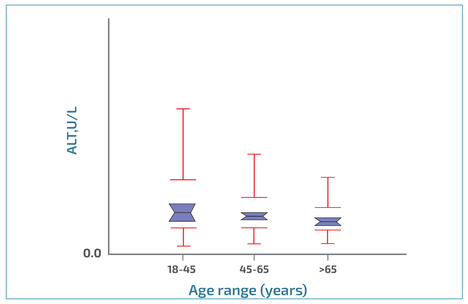
N=349	FIB-4 Presumed advanced fibrosis (≥2.68)	FIB-4 No Presumed advanced fibrosis (<1.3)	FIB-4 1.3-2.67 (indeterminate zone)
LSM Presumed advanced fibrosis (F3F4), ≥12KPa	**12 (3.4%)**	18 (5.2%)	53 (15.2%)
LSM No Presumed advanced fibrosis, <12KPa	7 (2.0%)	**172 (69.3%)**	17 (4.9%)

Among **70 (20.1%)** pts with indeterminate FIB-4 results, advanced fibrosis was presumed with LiverSTAT in 19pts and with LSM in 17 pts.

- In **11 (15.7%)** pts LiverSTAT and LSM agreed for AF and
- In **45 (64.3%)** pts. LiverSTAT and LSM agreed for non-AF.

Fibrosis presumed wth LiverSTAT Fibrosis score increases significantly with age while ALT enzymatic activity decreases with 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.

REFERENCES

1. Alkhouri N, Quiambao R, Munteanu M. Recommended clinical care pathways (CCPs) with FIB-4 underestimates the prevalence of advanced fibrosis (AF) compared to sequential CCP with Liverfast GP+ (GP+) and liver stiffness measurement (LSM) by Fibroscan. Hepatology. 2023 Oct 1;78(S1): S864 (2093-A)
2. Leow YW, Lai LL, Mustapha NRN, Mahadeva S, Quiambao R, Munteanu M and Chan WK. Validation of LIVERFASt-GP+ (GP+) as a noninvasive test for risk stratification for patients with Non-alcoholic Fatty Liver Disease (NAFLD): singlecentre study using liver biopsy as reference standard★ Hepatology 2023;78(S1): SS903 (2127-A)
3. Quiambao R, Hermabessière P, Delamarre A, Alam I, Munoz Perez JM, Lee J, Munteanu M. de Lédinghen V. LIVERFASt GP+, first-line screening tool in at-risk MAFLD patients outperforms the standard-of-care (SOC) FIB-4. Journal of Hepatology 2023 vol. 78(S1) | S674–S675

DISCLOSURES

MM: Fibronostics

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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 that lack sensitivity for advanced fibrosis detection, especially in aged patients.