

Comparative assessment of noninvasive methods (NIMs) - LIVERFAST, liver stiffness measurement (LSM) with transient elastography (TE, Fibroscan), ELF and FiB-4 - in a prospective cohort with chronic liver diseases (CLD) from a tertiary liver center

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INTRODUCTION

- CLD-related mortality in Thailand is increasing due to high prevalence of obesity and not eradicated chronic viral hepatitis B (CHB) and C (CHC)
- LIVERFAST™** (Fibrotestics, Florida, US) is a new point-of-care proprietary technology to assess quantitatively (normalized score from 0.00 to 1.00) liver fibrosis, steatosis and steatohepatitis in MAFLD patients. (1-3)
- LIVERFAST™** is a blood based serum biomarker that demonstrated prognostic value for liver-related events and overall mortality in MAFLD subjects (1)

AIMS

In a prospective tertiary cohort with CLD, to assess clinical performance against liver biopsy of different NIMs:

- 1/ For advanced and bridging fibrosis: LIVERFAST Fibrosis test, Enhanced liver fibrosis score (ELF), FIB-4 and LSM using vibration controlled transient elastography (VCTE).**
- 2/For steatosis (mild, moderate and marked): LIVERFAST Steatosis test and CAP (Fibroscan) in NAFLD patients, including a control group with CLD without steatosis (S0).**

METHODS

Patients

- Patients with NAFLD, CHB and CHC were prospectively included from a tertiary center (Khon Kaen University Hospital in Thailand).
- All patients had simultaneous liver biopsy, blood biomarkers (LIVERFAST, FIB-4 and ELF) and LSM using VCTE
- Biopsy staging was as per METAVIR in CHB/CHC patients and NASH-CRN in NAFLD patients.
- Statistics were descriptive and using area under ROC [AUROC (95%CI)].

CONCLUSIONS

- LIVERFAST is a blood biomarker for fibrosis and steatosis staging fibrosis and steatosis with similar performances to VCTE/CAP in patients with CLD.**
- LIVERFAST and VCTE outperformed ELF for staging advanced liver fibrosis.**
- LIVERFAST can be an alternative to imaging methods for stratifying patients with NAFLD and NASH.**

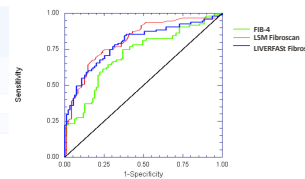
RESULTS

STUDY DESIGN



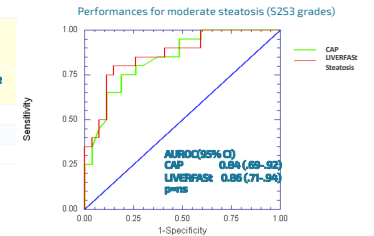
COMPARATIVE PERFORMANCES FOR FIBROSIS BETWEEN NIMs

| Overall cohort N=192 | AUROC (95%CI) for ADVANCED fibrosis | P value vs. LF |
|-------------------------|-------------------------------------|----------------|
| LIVERFAST Fibrosis (LF) | 0.81 (.67-.85) | |
| LSM (VCTE) | 0.70 (.62-.77) | ns |
| FIB-4 | 0.71 (.63-.77) | p<0.05 |



COMPARATIVE PERFORMANCES FOR STEATOSIS BETWEEN LIVERFAST AND CAP (Fibroscan)

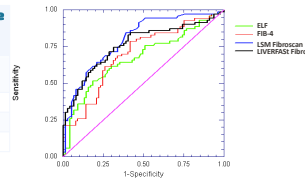
| NAFLD and control cohort (30 NAFLD, 17 controls S0) N=47 | AUROC (95%CI) | | P value |
|--|---------------------|-----------------|---------|
| | LIVERFAST Steatosis | CAP (Fibroscan) | |
| Mild steatosis ≥S1 | 0.86 (.70-.93) | 0.87 (.73-.94) | ns |
| Moderate steatosis ≥S2 | 0.86 (.71-.94) | 0.84 (.69-.92) | ns |
| Marked steatosis S3 | 0.81 (.62-.96) | 0.81 (.64-.91) | ns |



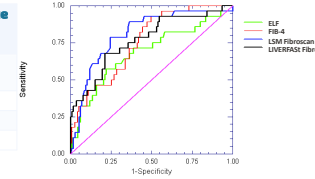
CHARACTERISTICS OF INCLUDED PATIENTS

| N=192 | Medians (range or SE) or % |
|----------------------------------|----------------------------|
| Male gender, % | 52.7% |
| Median (range) Age, yrs. | 50 (20-69) |
| BMI, Kg/m² | 23.9 (15.2-48.8) |
| HbA1c | 5.5% |
| Etiologies | |
| NAFLD | 26.4% |
| CHB | 23.9% |
| CHC | 49.8% |
| Liver biopsy | |
| Advanced fibrosis | 50.2% |
| Bridging fibrosis | 21.8% |
| Cirrhosis | 9.5% |
| Severe NAI | 49.5% |
| Moderate steatosis | 66.6% (among NAFLD) |
| Fibroscan | |
| Liver stiffness measurement, KPa | 7.5 (0.56-75) |
| CAP, dB/m | 216 (100-400) |
| LIVERFAST, medians (se) | |
| Fibrosis score | 0.29 (0.03-0.99) |
| Activity score | 0.29 (0.01-0.94) |
| Steatosis score | 0.35 (0.02-1.00) |
| ELF | 7.93 (3.97-12.98) |
| FIB-4 | 1.44 (0.14-7.52) |

| ELF cohort N=147 | AUROC (95%CI) for ADVANCED fibrosis | P value vs. LF |
|-------------------------|-------------------------------------|----------------|
| LIVERFAST Fibrosis (LF) | 0.77 (.61-.79) | |
| LSM (VCTE) | 0.79 (.71-.85) | ns |
| FIB-4 | 0.69 (.61-.77) | p<0.01 |
| ELF | 0.63 (.53-.71) | p<0.01 |



| ELF cohort N=147 | AUROC (95%CI) for BRIDGING fibrosis | P value vs. LF |
|-------------------------|-------------------------------------|----------------|
| LIVERFAST Fibrosis (LF) | 0.77 (.65-.85) | |
| LSM (VCTE) | 0.82 (.71-.88) | ns |
| FIB-4 | 0.75 (.63-.83) | ns |
| ELF | 0.64 (.49-.77) | ns |



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