Repeated noninvasive liver biopsy surrogate LIVERFASt TM correlates with BMI and liver enzymes improvements

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INTRODUCTION

- MAFLD-related morbi-mortality is increasing worldwide due to epidemics of obesity and type 2 diabetes (T2D). (2)
- **LIVERFASt** ™ (Fibronostics, 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 (1,4)

AIM

TO ASSESS LIVER FIBROSIS REGRESSION RATE (LFR) USING REPEATED LIVERFAST AND CORRELATIONS WITH IMPROVEMENTS IN CLINICAL ENDPOINTS, BODY MASS INDEX BMI ≥ 10% AND LIVER ENZYMES ALT ≥ 50% FROM BASELINE.

METHODS

Patients with repeated LIVERFASt prospectively included in a tertiary hepatology center.

Clinical endpoints considered for significant improvements assessment during follow up:

- **BMI** decrease of more than 10% from baseline value and
- **ALT** decrease more than 50% from baseline value.

Significant fibrosis stage improvement was considered with each **half of stage translated into 0.15** improvement in LIVERFASt score.

Fibrosis Progression Rate (FPR) used time dependent statistics cox Mantel hazard ratios HR (95%CI).

CONCLUSIONS

- **Half-stage liver fibrosis regression as presumed with LIVERFASt fibrosis score was significantly more likely in patients achieving ALT enzymatic activity improvement 50% or more from baseline values.**
- **A trend was observed in patients that achieving BMI improvement of 10% or more from baseline.**
- **LIVERFASt Fibrosis score correlates with clinical endpoints and, therefore, can be used for long-term monitoring of MAFLD patients.**

RESULTS

STUDY DESIGN

N=500 MAFLD patients PRE-INCLUDED
LIVERFASt at baseline

3.57 (max. **9.9**) yrs follow up

N=401 MAFLD patients INCLUDED
- having at least one repeated LIVERFASt measuremts during follow-up
- N=87 up to 7 repeated LIVERFASt measurements during follow-up

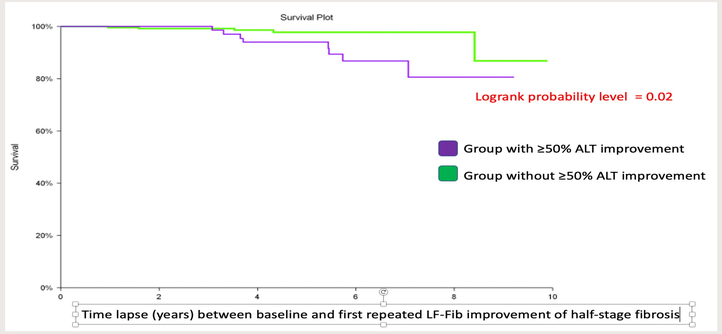
CHARACTERISTICS OF INCLUDED PATIENTS

N=401	
Male gender, %	44.3%
Median (range) Age	56 (21-77)
Presumed Fibrosis stages	
F0	45%
F1	29
F2	%
F3	6%
F4	12%
	8%
Presumed fibrosis regression according to LIVERFASt more than half stage (≥0.15) from baseline	13/401 (3.24%)
LIVERFASt median score (se)	0.27 (0.03)
Clinical endpoints (improvements from baseline)	
ALT ≥50%	109/401 (27.2%)
BMI ≥10%	75/401 (18.7%)
Median follow-up	9.9 years
Median (range) follow up (baseline to the last repeated LF-Fib)	3.57 years (3-9.9)

CUMULATIVE SURVIVALS OF PRESUMED LIVER FIBROSIS WITH LIVERFAST

Half-stage liver fibrosis improvement as per LIVERFASt was more likely among those patients that achieved ALT regression of 50% or more from baseline:

Cox Mantel Hazard Ratios [HR(95%CI)]:
3.47 (1.08-11.19) in the group with ALT regression lesser than 50% from baseline
versus
0.29 (0.09-0.93) in the group with ALT regression 50% or more
(logrank probability level 0.02)



MAFLD patients that achieved 10% or more in BMI improvement from baseline presented a trend to improve liver fibrosis (half stage) but without statistical significance HR (95%CI) 1.78 (0.38-8.39) vs 0.56 (0.12-2.64) in the group that not achieved a BMI improvement of ≥10% (logrank probability level =0.37).

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DOI: 10.3252/pso.eu.ILC2022.2022
FRI--089
ILC2022