Comparative performances of LIVERFASt™, VTCE™ (FibroScan) and other serum non-invasive tests (NITs) for the diagnosis of advanced chronic liver disease in non-alcoholic fatty liver disease (NAFLD) patients from a cohort with liver biopsy.

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Background

There is a call for action in the management of patients (pts) with type 2 diabetes mellitus (T2DM) and steatohepatitis (NASH) LIVERFASt™ (LF) is a serum-based proprietary panel for assessing fibrosis (LF-Fib), steatosis (LF-Ste) and activity (LF-Act) in NAFLD pts.

Aims

The main endpoints were the comparative diagnostic values of LF-Fib in NAFLD pts with or without T2DM for cirrhosis (F4) and severe fibrosis (F3F4) using liver stiffness measurements (LSM M/XL), Hepascore (HS), FibroSure (FS), FIB4, APRI and Forns, and liver biopsy (LB) as reference, in a prospectively collected cohort from 2003 in the University Hospital Center (CHU) of Bordeaux, France (NCT01241227).

Methods

Data was retrospectively compared among NAFLD pts with NITs and eligible for LB (advanced disease on LSM/function tests). LB scored NASH-CRN or SAF. Binary-AUROC (BinAUROC), 95%CI (p<0.05 vs 0.50) was used in per protocol (PP) and in-intention-to-diagnose (ITD), taking into account the non-applicability (N-A) rate for LSM. In cases with N-A LSM-M, LSM-XL values were used.

Results

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583/753 pts were included (170 missing/N-A NITs); 66/583 had N-A LSM. Pts characteristics were: 56.4% males, median age 56.4 yrs, 51.6%T2DM, BMI 31.5Kg/m^2, LSM 9.6KPa, CAP 324dB/m, 71% F2-F4, 17% F4, 71% S2S3, 51% A3A4.

LF-Fib binAUROC (95%CI) for F4 and F3F4 were 0.810 (.76-.85) and 0.720 (.68-.76), respectively, without differences between non-T2DM and T2DM neither for F4 [0.827 (.74-.89) vs. 0.788 (.72-.84), p=0.45] nor for F3F4 [0.736 (.67-.79) vs. 0.700 (.64-.75), p=0.39]. In ITD analysis (n=564), LF-Fib binAUROC (95%CI) for F4 was 0.800 (.75-0.84), not different from LSM [0.746 (.68-.80), p=0.08)], HS 0.774 (.71-.82), FS 0.805(.75-.85), FIB4 0.756 (.69-0.81), Forns 0.783(.73-.83), all p=ns, and superior to APRI [0.650(.59-0.71), p<0.001]; PP analysis had similar results, excepted for LF-Fib vs LSM [0.797 vs 0.807, p=0.02, respectively.

In ITD in T2DM pts (n=287), LF-Fib binAUROC (95%CI) for F4 was 0.774 (.70-.83), not different from LSM 0.720 (.63-.79), HS 0.748 (.67-0.81), FS 0.774 (.70-0.83), Forns 0.744 (.66-.81), all p=ns, and superior to FIB4 and APRI (p<0.001) (Figure 1) and without difference for F4 in non-T2DM (n=277) between LF-Fib and LSM [0.824 (.73-.89) vs 0.768 (.65-0.85), p=0.29, respectively].

Conclusion

LIVERFASt-Fibrosis is a NIT for the diagnosis of advanced chronic liver disease in NAFLD patients either in T2DM or non-T2DM pts. This score could be very useful to select patients for clinical trials and as screening test in general population.

Figure 1. Binary-AUROC for Cirrhosis in T2DM patients (n=287) for LIVERFASt-Fibrosis score, LSM (FibroScan), Hepascore, FibroSure, FIB4, Forns index and APRI.