Good Diagnostic Performance of Hepatoscope™ in Diabetology Clinics for the Screening of MASLD Patients with High Risk of Advanced Liver Fibrosis

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Introduction

The screening for metabolic dysfunction-associated steatotic liver diseases (MASLD)-related advanced fibrosis (AF) is recommended in patients with type 2 diabetes (T2D) and obesity with metabolic co-morbidities.
The Hepatoscope® is an ultraportable ultrasound system with two-dimensional transient elastography (2DTE) for liver stiffness measurement (LSM) (1-2).

Aim

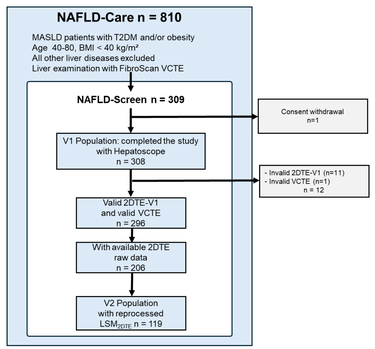
To evaluate the diagnostic performance of a new ultrasound imaging point-of-care device: Hepatoscope for the detection of patients with high risk of AF in diabetology.

Method

- Ancillary study from a prospective multicenter NAFLD-Care study (NCT04435054) (3) including participants willing to participate in the sub-study for the assessment of the diagnostic performance of the Hepatoscope™
  - Patients with MASLD and T2M and/or obesity, age 40-80 years, BMI < 40 kg/m².
  - 4 diabetes clinics in France
  - Enrollment between December 2022 and September 2024
  - Exclusion of all other liver etiologies
- LSM was performed on the same day using 2 ultrasound devices at the fasting state using :
  - Vibration controlled transient elastography (VCTE™) by FibroScan® and
  - Hepatoscope: Prototype version 2DTE-V1 for acquisition / post-acquisition reprocessing of data with CE-certified version (2DTE-V2)
- High risk of AF was determined using a hierarchical composite criteria: 1. Liver biopsy ≥ F3 if available or 2. Magnetic resonance elastography (MRE) ≥ 3.62 kPa or 3. VCTE ≥ 12 kPa as previously published (3)
- Statistical analysis: Spearman's correlation between VCTE and 2DTE-V1 or 2DTE-V2 in participants with valid VCTE (IQR/M ≤ 0.30) and AUROC and 95%CI for the detection of AF.
- Exploratory subgroup analysis performed in 48 participants with magnetic resonance imaging proton density fat fraction (MRI-PDFF) and backscattering coefficient (BSC) by Hepatoscope™ for the quantification of hepatic fat content.

Results

1.Study flowchart



2.Baseline characteristics of the study populations

	Population V1 (n=296)	Population V2 (n=119)	p-value V1 vs V2
Age (years)	61.0 [53.2 - 67.0]	60.0 [53.0 - 66.0]	0.40
Female (n, %)	127 (42.9)	44 (37.0)	0.32
T2D (n, %)	247 (83.4)	96 (80.7)	0.57
BMI (kg/m²)	32.5 [29.2 - 67.0]	32.2 [29.0 - 35.8]	0.54
Obesity (n, %)	210 (70.9)	82 (69.7)	0.81
Non-invasive tests			
FIB-4	1.34 [0.93 - 1.72]	1.32 [0.99 - 1.57]	0.64
LSM_{VCTE} (kPa)	6.1 [4.8 - 8.0]	6.8 [5.0 - 8.6]	0.14
FibroScan XL Probe (n,%)	126 (42.6)	36 (30.0)	0.0011
LSM_{MRE} (kPa) n=59	2.64 [2.28 - 3.00]	2.69 [2.31 - 3.36]	0.18
$LSM_{2DTE-V1}$ (kPA)	5.7 [4.4 - 7.5]	NA	
$LSM_{2DTE-V2}$ (kPA)	NA	7.1 [4.4 - 7.5]	NA
MRI-PDFF (%) n=59	10.0 [6.5 - 23.0]	10.0 [6.9 - 23.2]	0.61
CAP (dB/m)	306 [273 - 343]	303 [266 - 335]	0.41
BSC (dB/m.sr)	NA	- 19.8 [-28.3- -23.2]	NA
LSM_{VCTE} ≥ 8 (kPa) (n,%)	**74 (25.0)**	**38 (31.7)**	**0.18**
Presence of AF (n,%)*	**70 (8.9)****	**15 (12.7)**	**0.23**

** Presence of AF determined using hierachical composite criteria as follow: **n=25 with liver biopsy with n=10 ≥ F3; n=51 MRI with n=7 ≥ 3.6 kPa or overt cirrhosis; n=220 VCTE (n=14≥ 12kPa).*

3. Comparaison between LSM_{2DTE} and LSM_{VCTE}

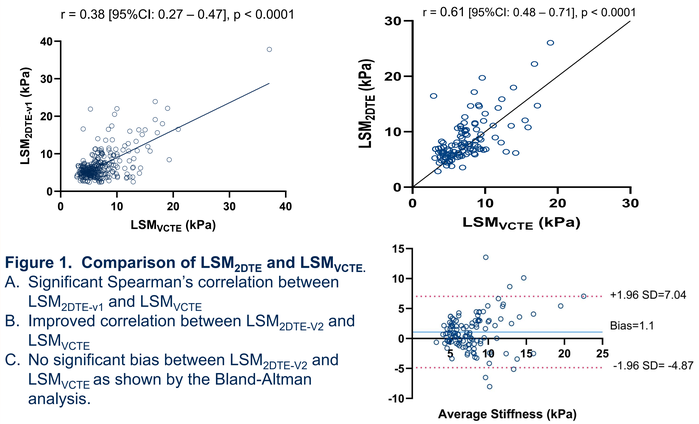


Figure 1. Comparison of LSM_{2DTE} and LSM_{VCTE}.
A. Significant Spearman's correlation between $LSM_{2DTE-V1}$ and LSM_{VCTE}
B. Improved correlation between $LSM_{2DTE-V2}$ and LSM_{VCTE}
C. No significant bias between $LSM_{2DTE-V2}$ and LSM_{VCTE} as shown by the Bland-Altman analysis.

4. Risk stratification for advanced fibrosis

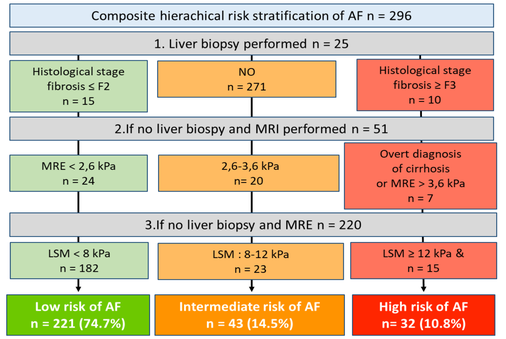


Figure 2. Composite score for stratification for risk of advanced fibrosis, based on liver biopsy, MRE and LSM_{VCTE}.

5. Hepatoscope performance to risk stratify patient for advanced fibrosis

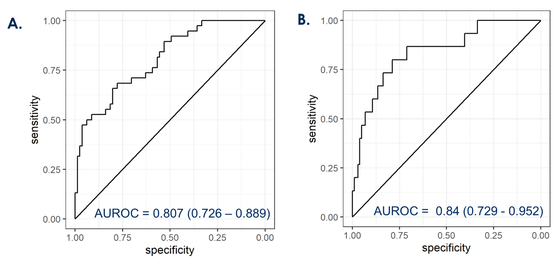


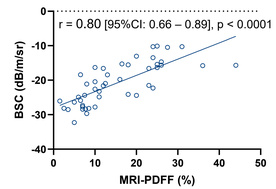
Figure 2. AUROC of Hepatoscope 2DTE-V2
A. to identify patients with LSM_{VCTE} > 8 kPa
B. to identify patients with high risk for advanced fibrosis (composite endpoint)

6. Risk stratification of patient for advanced fibrosis using LSM

	LSM < 8 kPa	8 ≤ LSM < 12	12 kPa ≤ LSM	p-value
LSM_{VCTE}	81	27	11	ns
LSM_{2DTE}	73	31	15	

Table 1. Risk stratification for advanced firbosis based on LSM.
No significant change of distribution (Fisher's exact test).

7.Correlation between BSC and MRI-PDFF



Conclusions

- This proof-of-concept study indicates that Hepatoscope™ 2DTE has **a good diagnostic performance for the identification of patients with high risk of AF** among patients with T2D and/or obesity screened in diabetology.
- Further studies in larger cohort using the 2DTE-V2 by Hepatoscope™ are needed to determine the optimal cut-offs.

References

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