Liver stiffness measurements with a new point-of-care device, Hepatoscope, using 2D transient elastography showed both very good reproducibility and correlation to Fibroscan

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1 Introduction

- **Liver stiffness measurement** (LSM) by transient elastography (TE) **is recommended in risk stratification** of patients at risk of NAFLD-NASH[1-3].
- Fibroscan® (FS) widely used in hepatology practice
- FS provides a **1D-measurement of shear wave speed** (VCTE).
- Affordable, reproducible and reliable LSM are needed for **large-scale screening** of NAFLD-NASH at the point of care (and in primary care).

2 Aim

- To assess the **reproducibility of LSM** on a new ultrasound point-of-care device, Hepatoscope™, with:
  - TE using **2D-measurements** of shear wave speed (2DTE),
  - Ultrasound **imaging guidance**
- To **compare 2DTE LSM** with **FS VCTE**

3 Method

- **Prospective** single centre study (NCT04782050)
- 96 adult patients referred to routine outpatient hepatology consultation for CLD
- **1 expert and 1 novice operators**, blinded to any median value for each series of measurements
- Four Hepatoscope exams performed to assess the **intra-operator** and **inter-operator reproducibility** of LSM
- LSM estimated using the median of 4 (LSM_{Med4}) or 15 (LSM_{Med15}) stiffness values with different quality levels
- Reproducibility assessed by Intraclass Correlation Coefficients (ICC)
- Correlation between LSM by experts assessed with r^2 coefficient

4 Results

Fig 1. Breakdown of aetiologies of chronic liver diseases in the recruited population

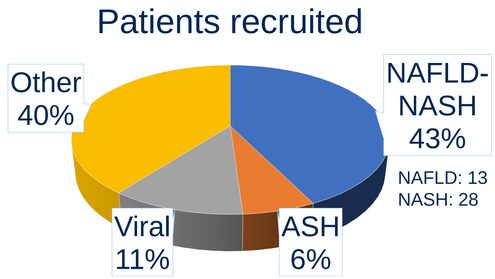
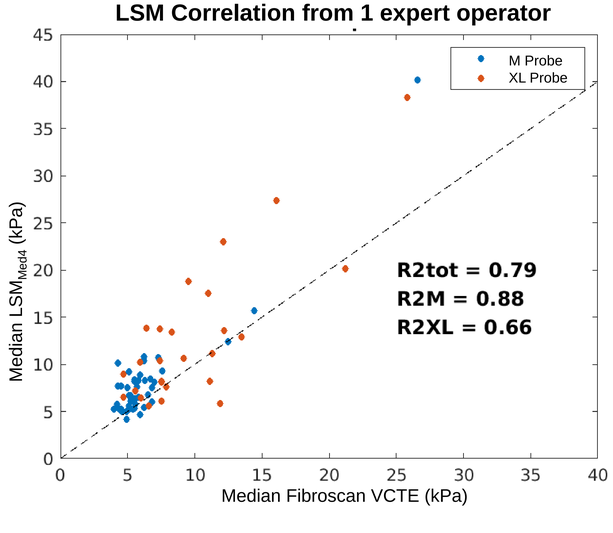


Table 1. ICC values for intra-operator repeatability (for experts and novices) and inter-operator reproducibility of LSM obtained with Hepatoscope.

ICC values	LSM_{Med15}	LSM_{Med4}
Experts repeatability	0.90; 95%CI [0.85-0.93]	0.89; 95%CI [0.85-0.93]
Novices repeatability	0.76; 95%CI [0.66-0.83]	0.81; 95%CI [0.73-0.87]
Reproducibility	0.83; 95%CI [0.78-0.88]	0.85; 95%CI [0.80-0.89]

Fig 2. Correlation graph between LSM performed by Hepatoscope and Fibroscan using any, the M or the XL probe.



5 Conclusions

- LSM **can be performed** with 2DTE at the point-of-care device Hepatoscope **by experts and novices**.
- Hepatoscope LSM could be defined as the median of **only 4 values** of high-enough quality.
- LSM measured with Hepatoscope showed **good correlation** with Fibroscan.
- Future studies against liver histopathology should validate **existing LSM cutoff values** for the screening and triage of patients at risk of fibrotic NASH.

6 References

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2. **Kanwal F et al.** Clinical Care Pathway for the Risk Stratification and Management of Patients With Nonalcoholic Fatty Liver Disease. *Gastroenterol 2021;161(5):1657-1669*

3. **Cusi K et al.** American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings. *Endocr Pract 2022;28(5):528-562.*

7 Contact information

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Hepatoscope 2DTE and LSM show promises for large scale screening at the point of care.

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