

LSM in patients with MASLD using Hepatoscope® is comparable to Fibroscan® and not affected by BMI

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Abstract

Background
In obese patients, abdominal fat may affect the reliability of liver stiffness measurement (LSM) with FibroScan®VCTE as studies show accuracy rates of 60% in populations with BMI >40. Ultrasound (US) is often required to find the best location for LSM, extending time and cost. Screening of patients with metabolic-dysfunction associated liver disease (MASLD) could benefit from a portable US imaging system with associated transient elastography (TE) to risk-stratify liver fibrosis. The aim of this study was to evaluate Hepatoscope® (E-scopics Inc.), an 2D-US portable device with associated TE in patients with MASLD at differing BMI levels, and to assess its non-inferiority as compared to FibroScan (Echosens Inc).

Methods
From August to December 2024, 174 MASLD patients scheduled for FibroScan exam at Mercy Medical Center were enrolled in this prospective study. The patients underwent a second exam with Hepatoscope 2DTE (v2.1.5). LSM_{VCTE} was valid if there were 10 or more exams with interquartile range/median ratio below 30%.. LSM_{VCTE} and LSM_{2DTE} were compared by a Mann-Whitney test, Spearman’s correlation with a Deming regression model. Impact of body mass index (BMI) on both LSM_{VCTE} and LSM_{2DTE} was assessed.

Results
174 patients were evaluated using both tests . Baseline demographics included median age 59.0 [48.3 - 67.0], BMI 30.82 [26.99 - 35.45], 97 (53.8%) female, 99 (55.0%) had BMI> 30 with 20 (11.6%) with BMI > 40. 102 (56.7%) had type 2 diabetes. Distributions of LSM_{2DTE} and LSM_{VCTE} were not significantly different (5.4 kPa [4.4 - 7.7] and 6.1 kPa [4.6 - 9.0], respectively). They both correlated strongly (r = 0.64, 95%CI: 0.5532 - 0.7281) and there was no significant bias. LSM_{VCTE} had a weak but significant trend to increase with BMI (r = 0.2633 95%CI: 0.1149 - 0.4003, p = 0.0004) and patients with severe obesity (BMI > 40 kg/m²) had higher LSM_{VCTE} (p = 0.011). This was not observed with Hepatoscope where LSM_{2DTE} measurements were found to be independent of BMI.

Conclusion
Hepatoscope is a solution for the accurate assessment of LSM in MASLD patients, combining TE and 2D-US imaging, that is FDA approved with CPT codes for billing. Our study demonstrated that Hepatoscope results are non-inferior to FibroScan for LSM assessment. LSM_{2DTE} measurements were independent of BMI, potentially addressing the limitations of other devices. Hepatoscope may offer additional advantages over FibroScan due to its portability and integrated 2D imaging capability.

Introduction

- FibroScan VCTE is a device commonly used for LSM.
- There are limitations to FibroScan that prompt evaluation of alternative forms of 50 Hz TE for LSM:
 - Obesity, particularly BMI >40, can affect the accuracy of FibroScan.
 - US is needed for localization prior to LSM, increasing length and cost of exam.
- A highly portable combined TE and 2D-US (2DTE) imaging system capable of LSM would expand access for MASLD screening.
- In our study we evaluated Hepatoscope in patients with MASLD and variable BMIs to asses its non-inferiority to FibroScan.

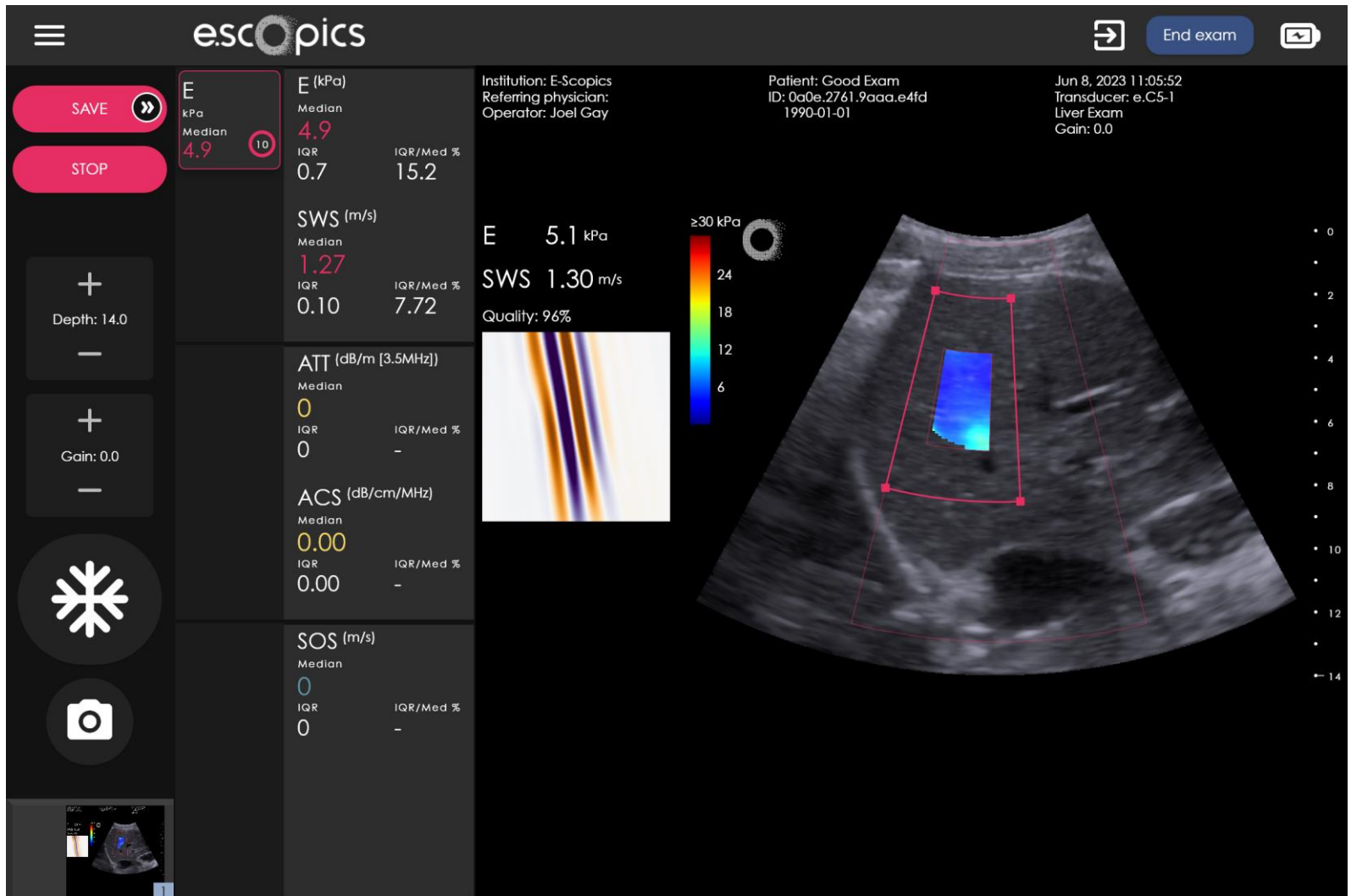


Figure 1. Hepatoscope 2DTE-LSM interface.

Methods and Materials

- Location: Mercy Medical Center, Baltimore, MD.
- Data collection: From August to December 2024.
- Population: 174 MASLD patients enrolled in this prospective study.
- LSM performed with both FibroScan and Hepatoscope.
- LSM_{VCTE} was valid if there were ≥10 exams with interquartile range/median ratio <30%.
- LSM_{VCTE} and LSM_{2DTE} were compared by a Mann-Whitney test, Spearman’s correlation with a Deming regression model.
- Impact of body mass index (BMI) on both LSM_{VCTE} and LSM_{2DTE} was assessed.

Population Demographics

Median Age, Years	59.0 [48.3 - 67.0]
Median BMI, kg/m ²	BMI 30.82 [26.99 - 35.45]
Sex (Female), n (%)	97 (53.8%) female
BMI (>30), n (%)	99 (55.0%)
BMI (>40), n (%)	20 (11.6%)
Type 2 Diabetes, n (%)	102 (56.7%)

Table 1. Population demographics.

Results

- 174 patients were evaluated using both tests.
- Baseline demographics as seen in the table above.
- No significant difference seen between LSM_{2DTE} (5.4 kPa [4.4 - 7.7]) and LSM_{VCTE} (6.1 kPa [4.6 - 9.0]).
- A strong correlation was seen (r = 0.64, 95%CI: 0.5532 - 0.7281) with no significant bias.
- LSM_{VCTE} increased with BMI (r = 0.2633 95%CI: 0.1149 - 0.4003, p = 0.0004).
- Patients with severe obesity (BMI > 40 kg/m²) had higher LSM_{VCTE} (p = 0.011).
- LSM_{2DTE} measurements were found to be independent of BMI.

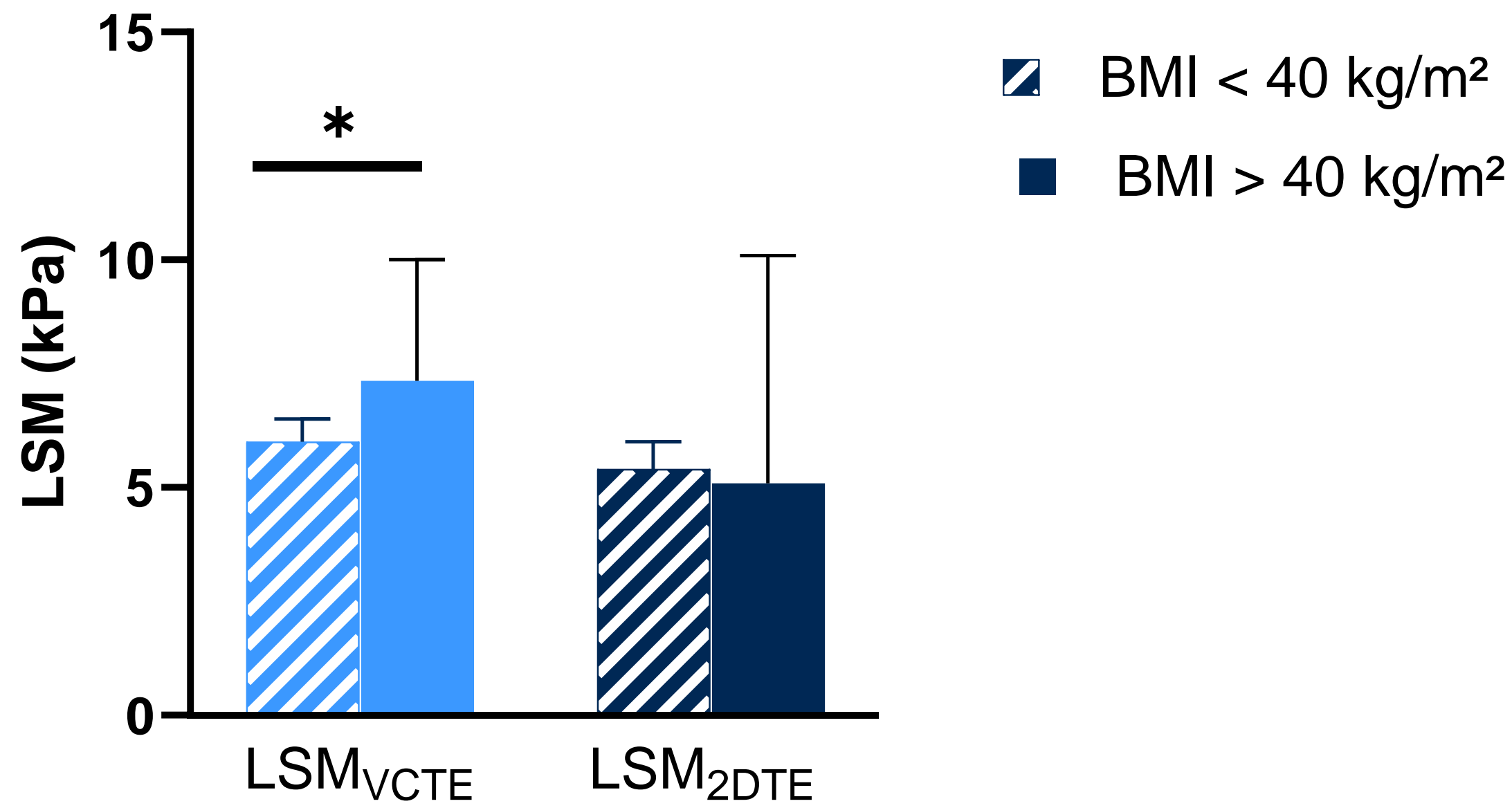


Chart 1. LSM when adjusted for BMI for FibroScan (light blue) and Hepatoscope (dark blue).

Discussion

- Our study demonstrated that Hepatoscope results are non-inferior to FibroScan for LSM assessment.
- Not only is Hepatoscope non-inferior to FibroScan, but we also found that LSM_{2DTE} measurements were independent of BMI, while LSM_{VCTE} measurements were skewed higher with increasing BMI.
- Combining TE and 2D-US imaging reduces the need for dedicated US localization.
- Easy portability increases improves access to sites without LSM capabilities.



Figure 2. Hepatoscope device.

Conclusions

- Hepatoscope addresses many limitations of FibroScan, including:
 - More accurate LSM in higher BMI (>40) patients thanks to 2-dimensional measurements of TE.
 - Combined TE and 2D-US.
 - Increased portability.
- These factors suggest that while not only being non-inferior to FibroScan for LSM assessment, Hepatoscope may also offer additional benefits.

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