

STUDY TITLE:

**EUS-Guided Attenuation Imaging and Shear Wave Elastography
in Individuals with Normal Fibro Scan: Establishing Preliminary
Reference Values in a Pilot Feasibility Study**

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1. INTRODUCTION

Vibration-controlled transient elastography (VCTE) and Controlled Attenuation Parameter (CAP) are established non-invasive methods for assessing liver fibrosis and steatosis. However, they have technical limitations including failure in obese patients and lack of real-time imaging guidance. Endoscopic ultrasound (EUS)-guided Attenuation Imaging (ATI) and Shear Wave Elastography (SWE) allow direct visualization of liver parenchyma and may provide more reliable quantitative assessment. Normal reference values for EUS-guided ATI and SWE have not yet been established.

2. RATIONAL

EUS enables close-proximity imaging of both hepatic lobes and minimizes interference from adipose tissue and bowel gas. Establishing normal reference values for EUS-guided ATI and SWE is essential before these technologies can be evaluated for diagnostic use in liver disease.

3. STUDY OBJECTIVES

3a. Primary Objective

- To establish preliminary reference values for EUS-guided ATI of the right and left hepatic lobes.
- To establish preliminary reference values for EUS-guided SWE elasticity (kPa) and velocity (m/s) in both hepatic lobes.

3b. Secondary Objectives

- To assess technical feasibility of EUS-guided ATI and SWE.
- To evaluate agreement between right and left lobe measurements.
- To determine correlations between ATI and FibroScan CAP.
- To determine correlations between SWE and FibroScan LSM.
- To determine acquisition time for ATI and SWE.
- To evaluate measurement reliability and reproducibility.

4. STUDY POPULATION

Adults undergoing diagnostic EUS for non-hepatobiliary indications with normal FibroScan findings.

5. DESIGN AND DURATION OF THE STUDY

Prospective, single-center, observational pilot feasibility study. Target enrollment: 100 subjects. Estimated study duration: Until completion of recruitment and analysis.

6. METHODOLOGY

6a. INCLUSION / EXCLUSION CRITERIA

Inclusion Criteria:

- Age ≥ 18 years.
- Undergoing diagnostic EUS.
- Same-day FibroScan available.
- CAP < 238 dB/m.
- LSM < 7.5 kPa.
- ≥ 10 valid FibroScan measurements.
- FibroScan IQR/Median $\leq 30\%$.
- Written informed consent.

Exclusion Criteria:

- Known chronic liver disease.
- Hepatitis B or C infection.
- Significant alcohol consumption.
- Decompensated cirrhosis.
- Portal vein thrombosis.
- Ascites.
- Focal liver lesion.
- Previous liver surgery.
- Pregnancy.
- Inadequate FibroScan examination.
- Poor-quality ATI or SWE acquisition.
- Incomplete study data.

6b. STUDY MEDICATIONS

Not applicable. No investigational drug will be administered.

6c. SUBJECT RECRUITMENT

Eligible patients undergoing diagnostic EUS at AIG Hospitals will be screened and recruited after obtaining written informed consent.

6d. RANDOMIZATION AND BLINDING

Not applicable. This is an observational study with no randomization or blinding.

6e. STUDY METHODS / STUDY PROCEDURE / METHODS OF ASSESSMENT

Step 1: FibroScan Assessment

- CAP and LSM recorded.
- Minimum 10 valid measurements.
- IQR/Median ratio documented.

Step 2: EUS-Guided ATI

- Left lobe assessed transgastrically.
- Right lobe assessed transduodenally.
- Five valid ATI measurements per lobe.
- $R^2 \geq 0.80$ required for acceptable measurements.
- Mean, median, SD, IQR and acquisition time recorded.

Step 3: EUS-Guided SWE

- Ten valid SWE measurements per lobe.
- Propagation maps used for quality assessment.
- Velocity (m/s) and elasticity (kPa) recorded.
- Reliability assessed using IQR/Median ratio.
- Acquisition time documented.

Baseline demographic, clinical and laboratory variables will also be collected.

6f. STOPPING OR DISCONTINUATION CRITERIA

Subjects may be excluded from final analysis if:

- FibroScan quality criteria are not met.
- ATI or SWE quality criteria are not met.
- Study data are incomplete.
- Consent is withdrawn.

7. OUTCOME MEASURES

7a. Primary Outcomes

Reference values for:

- ATI (right and left hepatic lobes).
- SWE elasticity (right and left hepatic lobes).
- SWE velocity (right and left hepatic lobes).

Results will be reported as mean $\pm$ SD, median (IQR), and 95% reference intervals.

7b. Secondary Outcomes

- Technical success rate.
- Measurement reliability.
- Right-left lobe agreement.
- Correlation with FibroScan CAP and LSM.
- ATI acquisition time.
- SWE acquisition time.

8. SAMPLE SIZE CALCULATION

A target sample size of 100 subjects with normal FibroScan findings has been selected to provide stable preliminary estimates of EUS-guided ATI and SWE reference ranges. Interim analysis will be performed after recruitment of the first 30–50 participants.

9. STATISTICAL ANALYSIS

- Continuous variables will be expressed as mean $\pm$ SD and median (IQR).
- Reference intervals will be derived using non-parametric percentile methods.
- Spearman's rank correlation will assess relationships between EUS and FibroScan parameters.
- Bland–Altman analysis and Intraclass Correlation Coefficients (ICC) will evaluate agreement between hepatic lobes.
- A p-value <0.05 will be considered statistically significant.

10. ETHICAL JUSTIFICATION OF THE STUDY

The study is observational and involves procedures performed during clinically indicated EUS examinations. No investigational drug or additional invasive intervention is required beyond standard care. Risks are minimal, and the knowledge gained may support future development of EUS-based quantitative liver assessment techniques.