Comparison between Fibroscan and Hepatus for Detecting NAFLD in Patients with Metabolic Dysregulation

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ABSTRACT

Background *The clinical application of the innovative instantaneous elasticity technology is currently in the evaluation stage. This study aimed to compare the detection performance of Fibroscan and Hepatus in detecting nonalcoholic fatty liver disease (NAFLD) among patients with metabolic dysregulation.*

Methods *This prospective study was conducted between January 2021 and April 2021 with 149 patients enrolled. Clinical data were collected, and all patients underwent both Fibroscan and Hepatus to determine liver stiffness measurement (LSM) and attenuation parameters. Pearson correlation analysis and scatter diagram were used to analyze the correlation, while a paired t-test was used to compare the differences between the detected values from the two machines. Receiver operating characteristic curves (ROC) were constructed to compare the diagnostic cut-off for Hepatic Steatosis Index (HSI)-based NAFLD.*

Results *The detection success rate of Hepatus (100.0%) was higher than that of Fibroscan (96.0%). And we found that the LSM (r = 0.663, P<0.001) and attenuation parameters (r = 0.778, P<0.001) obtained by Fibroscan and Hepatus were significantly correlated. Hepatus tended to produce a higher LSM value (Hepatus vs. Fibroscan: 6.04 vs. 5.66 kPa, P=0.016), but a lower attenuation parameter value than Fibroscan (Hepatus vs. Fibroscan: 264 vs. 277 dB/m, P<0.001). The area under the ROC curve for detecting HSI-based NAFLD was 0.811 for Fibroscan and 0.832 for Hepatus.*

Conclusion *Measurements obtained by Fibroscan and Hepatus are highly correlated, and the diagnostic value of the two TE devices is comparable in detecting HSI-based NAFLD.*

Keywords *hepatic steatosis, liver stiffness, NAFLD, transient elastography*

ABSTRAK

Latar Belakang*: Penerapan klinis teknologi elastisitas sesaat yang inovatif-Hepatus, saat ini sedang dalam tahap evaluasi. Penelitian ini bertujuan untuk membandingkan kinerja deteksi Fibroscan dan Hepatus dalam mendeteksi penyakit hati berlemak nonalkohol (NAFLD) pada pasien dengan disregulasi metabolik.*

***Metode**: prospektif ini dilakukan antara Januari 2021 dan April 2021 dengan 149 pasien terdaftar. Data klinis dikumpulkan, dan semua pasien menjalani Fibroscan dan Hepatus untuk menentukan pengukuran kekakuan hati (LSM) dan parameter atenuasi. Analisis korelasi Pearson dan diagram sebar digunakan untuk menganalisis korelasi, sedangkan uji t berpasangan digunakan untuk membandingkan perbedaan nilai yang terdeteksi dari dua mesin. Kurva karakteristik operasi penerima (ROC) dibuat untuk membandingkan batas diagnostik untuk NAFLD berbasis Indeks Steatosis Hepatik (HSI).*

***Hasil**: Tingkat keberhasilan deteksi Hepatus (100,0%) lebih tinggi dibandingkan Fibroscan (96,0%). Dan kami menemukan bahwa LSM (r = 0,663, P<0,001) dan parameter atenuasi (r = 0,778, P<0,001) yang diperoleh oleh Fibroscan dan Hepatus berkorelasi secara signifikan. Hepatus cenderung menghasilkan nilai LSM yang lebih tinggi (Hepatus vs. Fibroscan: 6.04 vs. 5.66 kPa, P=0.016), namun nilai parameter atenuasi lebih rendah dibandingkan Fibroscan (Hepatus vs. Fibroscan: 264 vs. 277 dB/m, P<0.001). Area di bawah kurva ROC untuk mendeteksi NAFLD berbasis HSI adalah 0,811 untuk Fibroscan dan 0,832 untuk Hepatus.*

***Kesimpulan**: Pengukuran yang diperoleh Fibroscan dan Hepatus sangat berkorelasi, dan nilai diagnostik kedua perangkat TE sebanding dalam mendeteksi NAFLD berbasis HSI.*

***Kata kunci:** steatosis hati, kekakuan hati, NAFLD, transient elastography*

INTRODUCTION

Concurrent with the global obesity epidemic, the prevalence of non-alcoholic fatty liver disease (NAFLD) has surged by +50.4%, escalating from 25.3% in 1990-2006 to 38.0% in 2016-2019 worldwide(1). NAFLD is regarded as the most common liver disease in the 21st century, and a condition leaving individuals at increased risk of extra-hepatic morbidity (2, 3). Despite its widespread impact, there is currently no approved pharmacological treatment for NAFLD(4). Consequently, the assessment of liver steatosis and stiffness severity has emerged as a pivotal concern for early management and intervention. Transient elastography (TE) as an ultrasound-based technique has become a crucial non-invasive diagnostic technology for evaluating liver steatosis and stiffness. Globally acknowledged and widely adopted, TE stands out as one of the most extensively utilized methods(5-8). TE can reflect the degree of liver stiffness by measuring liver stiffness measurement (LSM)(9), and evaluate the degree of liver steatosis by measuring attenuation parameter (10). Its non-invasive, painless, and easily operable nature has contributed to the high acceptance among patients.

In 2003, Echosens introduced Fibroscan, utilizing Vibration-controlled transient elastography (VCTE) technology for measuring tissue elasticity. Over the years, Fibroscan has found widespread application in clinical practice, demonstrating its effectiveness in assessing liver fibrosis and steatosis across diverse liver diseases (11, 12). Evidence showed that both controlled attenuation parameters (CAP) and LSM by Fibroscan have high accuracy in predicting the steatosis and fibrosis stage in NAFLD patients(13-15). Recently, a new TE device based on visual transient elastography (ViTE) technology was introduced by Shenzhen Mindray Company (China), which was named Hepatus. It has been shown that both Fibroscan and Hepatus are effective tools for staging liver stiffness and steatosis in patients with chronic hepatitis B, which can provide high sensitivity and immediate results (16, 17). Notably, while the diagnostic performance of Fibroscan in various liver diseases has been extensively studied, there is a current gap in the literature regarding the detection capabilities of Hepatus in liver diseases caused by other etiologies, such as NAFLD.

As NAFLD poses a significant health challenge globally, understanding the comparative diagnostic capabilities of these technologies becomes crucial for enhancing early detection and management strategies. The clinical application of Hepatus is presently undergoing evaluation, necessitating further studies to comprehensively assess its accuracy and effectiveness in evaluating liver fibrosis and steatosis. In this study, our focus is on comparing the detection performance of two used TE devices, Fibroscan and Hepatus. Specifically, we aim to evaluate their efficacy in patients with metabolic dysregulation.

METHODS

1. Study design and participants

This study was a prospective study carried out at the National Metabolic Management Center (MMC) of the first affiliated hospital of Ningbo University, from January 2021 to April 2021. We recruited patients

who had metabolic dysregulation and received both Fibroscan and Hepatus examinations. The diagnostic criterion for metabolic dysregulation satisfied at least one of the following conditions(18): (1) overweight/obesity [Body mass index (BMI) ≥ 24 kg/m^2] (19); (2) type 2 diabetes mellitus (T2DM, according to ADA criteria); and (3) presence of metabolic syndrome(20). Participants were excluded if they met the following criteria: (1) aged less than 18 years or more than 75 years; (2) incomplete medical history; (3) history of viral hepatitis, autoimmune hepatitis, drug-induced liver injury, and Wilson's disease; (4) pregnant women; (5) has unhealed wounds in the right upper abdomen. A flowchart of the study design and the patient enrollment procedure is shown in **Figure 1**.

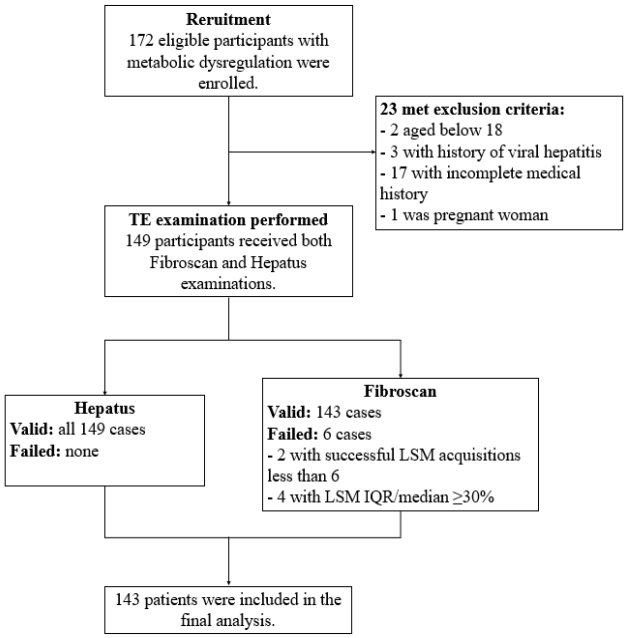


Figure 1. Study flowchart.

This study was approved by the Ethics Committee of the first affiliated hospital of Ningbo University (Approval No. 2019-R057), and written informed consent was obtained from all patients.

2. Clinical and laboratory examination

Clinical and laboratory data were collected according to the MMC standard procedure by trained nurses or laboratory staff (21). Anthropometric indicators were measured according to standard procedure. Height (cm) and weight (kg) were measured using a calibrated automatic digital weight and height scale (HNH-318, Omron, Japan). Waist and hip circumference (cm) were measured by rubber tape. BMI (kg/m^2) was calculated using the formula of weight (in kg) divided by height squared (in m). The waist-to-hip ratio (WHR) was calculated in waist circumference divided by hip circumference. Abdominal obesity was defined as a waist circumference of ≥90 cm in men and ≥80 cm in women(20).

Elbow venous blood was collected after overnight fasting. Automatic biochemical analyzer (AU5421, Beckman, USA) was used to detect biochemical indicators including alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyltransferase (GGT), fast plasma glucose (FPG), triglyceride (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C). Glycosylated hemoglobin (HbA1c) (%) was analyzed using high-performance liquid chromatography (HPLC) (D-10 Hemoglobin Analyzer, Bio-Rad, USA). All biochemical parameters were detected by standard automated laboratory methods using commercially available kits following the manufacturer's protocols. The Hepatic steatosis index (HSI) score was calculated in all patients using the following formula: 8 × (ALT / AST) + BMI + 2 (if type 2 diabetes) + 2 (if female)(22). HSI score of > 36 predicted the presence of hepatic steatosis and was defined as "HIS-based NAFLD" in this study(23).

3. Transient elastography examination

The TE machines used in this study were Fibroscan (PRO, probe type: M or XL, Echosens, France) and Hepatus (Resona 6W, probe type: LFP5-1S, Mindray, China), respectively. Each patient accepted two TE examinations in random order in different rooms after fasting for more than 2 hours. Both TE machines were conducted to evaluate liver stiffness and hepatic steatosis by the same experienced operator, who had performed more than 300 times examinations before this study.

Fibroscan examination

During the Fibroscan examination, participants were asked to stay in the dorsal decubitus position with their right arms extended and lifted, and the probe was placed over the region of the right 7th-9th intercostal spaces. After at least 10 measurements at the same position, the LSM (kPa) and the controlled attenuation parameter (CAP, dB/m) were obtained. The Median and Interquartile Range (IQR) of each measurement for LSM and CAP was reserved as the final reported

detection value, and IQR/Median was calculated. The use of the Fibroscan probe (M or XL) depended on the automatic probe recommendation tool. An examination was considered valid if there were at least 6 successful acquisitions and an interquartile range/median of the measurements ≥ 30%(24). CAP ≥ 248 dB/m was considered suggestive of steatosis and diagnosed as NAFLD in this study(25).

Hepatus examination

Hepatus is a newly developed ultrasound machine with a 3.5-MHz phased-array probe, which can provide real-time synchronous two-dimensional (2D) ultrasound images and has a pressure sensor(17). When performing the Hepatus examination, the operator obtained real-time 2D ultrasound images through the probe to select the target area of interest for examination, avoiding the gallbladder, liver capsule, adipose layer, and large blood vessels **(Figure 2)**. Other steps were consistent with the Fibroscan examination. Finally, the LSM and liver ultra-sound attenuation (LiSA) parameters were obtained. Similar to CAP, LiSA is also a sound attenuation parameter corresponding to the 3.5mhz ultrasonic wave, and the two parameters are comparable.

4. Statistical analysis

Continuous variables were expressed as the mean ± standard deviation ($\bar{X}$±s) in a normal distribution and tested using the *t-test*, or expressed as the M (IQR) in a nonnormal distribution when the Kruskal-Wallis *H* test was used. Categorical variables are expressed as n (%) and were tested using the ^{2} test. Bland Altman plot was used to analyze the agreement between measurements obtained using the two machines. Pearson correlation analysis and scatter diagram were used to analyze the correlation of detection results of two TE machines. A paired *t-test* was used to compare the LSM and attenuation parameters obtained by two TE machines and their IQR and IQR/M. Receiver Operating Characteristic (ROC) curves were constructed, and the area under the ROC curves (AUC) was calculated to assess the diagnostic efficiency of HSI-based NAFLD. Statistical significance was set at a *P* value < 0.05 for the two-sided test. All statistical analyses were performed using R 4.3.0 (R Core Team).

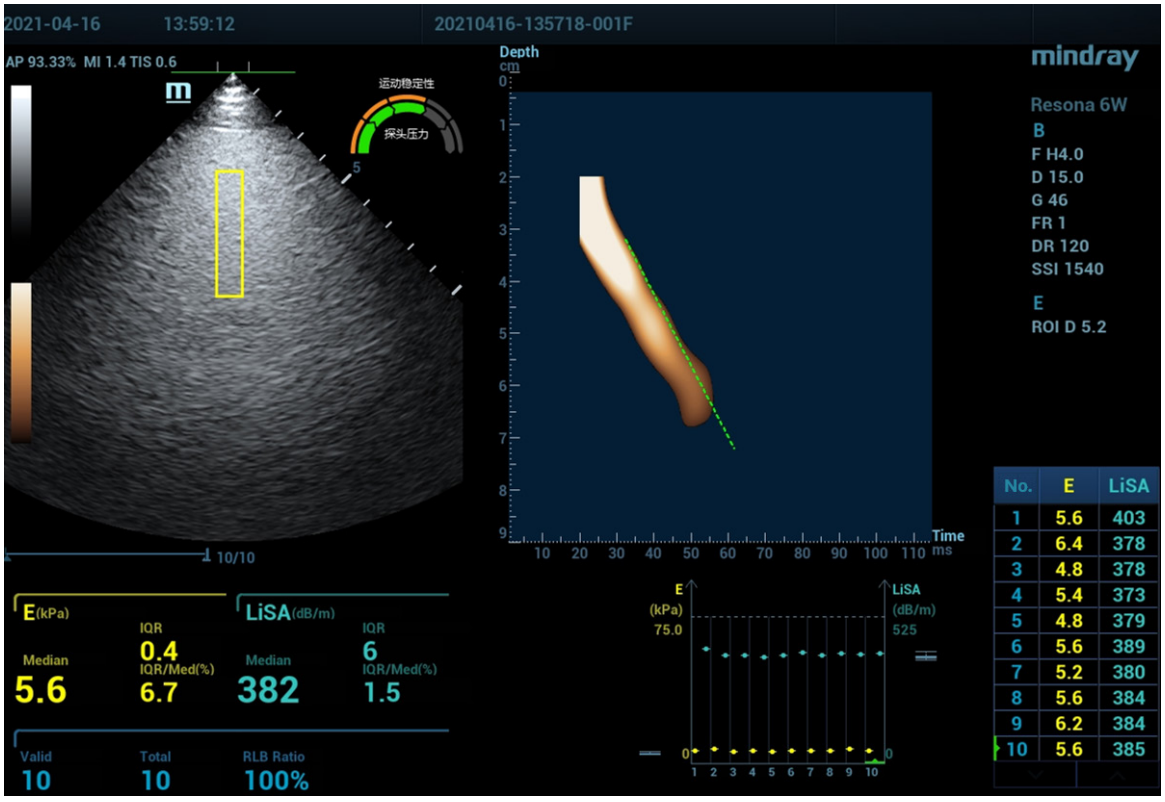


Figure 2. The data acquisition process using ViTE by Hepatus (Reaona 6W). The picture on the left is a 2-dimensional grayscale image used for guiding probe placement, with the final liver fibrosis measurement (LSM, kPa) and liver ultra-sound attenuation (LiSA, dB/m) parameter obtained by ViTE. The picture on the right shows the propagation path for the main sound beam for ViTE.

Table 1. Baseline characteristics for continuous variables.

	Overpopulation (n=143)	non-NAFLD (n=44)	NAFLD (n=99)	P
Age, years	42.7 ± 13.7	46.5 ± 11.3	41.0 ± 14.4	**0.017**
BMI, kg/m^2	28.5 ± 5.2	25.4 ± 3.2	29.8 ± 5.4	**<0.001**
Waist circumference, cm	95.8 ± 11.9	89.1 ± 9.2	98.6 ± 11.9	**<0.001**
WHR	0.94 ± 0.07	0.92 ± 0.06	0.95 ± 0.07	**0.006**
ALT, IU/L	25.0 (20.0)	20.0 (12.2)	30.0 (30.5)	**<0.001**
AST, IU/L	21.0 (20.0)	18.5 (7.0)	23.0 (12.5)	**<0.001**
ALP, IU/L	77.0 (27.0)	71.0 (34.8)	78.0 (20.0)	0.102
GGT, IU/L	26.0 (23.0)	17.5 (13.3)	28.0 (25.5)	**0.004**
FPG, mmol/L	6.03 (2.91)	6.13 (2.89)	5.99 (2.93)	0.938
HbA1c (%)	6.3 (2.3)	6.5 (1.6)	6.1 (2.4)	0.598
TC, mmol/L	5.08 ± 1.34	4.78 ± 1.31	5.21 ± 1.33	0.072
TG, mmol/L	1.49 (1.17)	1.13 (0.79)	1.63 (0.80)	**0.048**
HDL-c, mmol/L	1.22 ± 0.22	1.25 ± 0.24	1.21 ± 0.22	0.463
LDL-c, mmol/L	3.37 ± 1.01	3.16 ± 0.98	3.46 ± 1.02	0.095

Abbreviations: WHR, waist-to-hip ratio; DBP, diastolic blood pressure; SBP, systolic blood pressure; VFA, visceral fat area; SFA, subcutaneous fat area; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ALP, alkaline phosphatase; GGT, γ-glutamyltransferase; FPG, fasting plasma glucose; HbA1c, glycated hemoglobin; TC, total cholesterol; TG, triglycerides; HDL-c, high-density lipoprotein cholesterol; LDL-c, low-density lipoprotein cholesterol.

Table 2. Baseline characteristics for categorical variables.

	Overpopulation (n=143)	non-NAFLD (n=44)	NAFLD (n=99)	P
Male	76 (53.1)	26 (59.1)	50 (50.5)	0.442
Female	67 (46.9)	18 (40.9)	49 (49.5)	0.562
Obesity	67 (46.9)	30 (68.2)	88 (88.9)	**<0.001**
Abdominal obesity	119 (83.2)	27 (61.4)	92 (92.9)	**<0.001**
T2MD	70 (49.0)	23 (52.3)	47 (47.5)	0.728

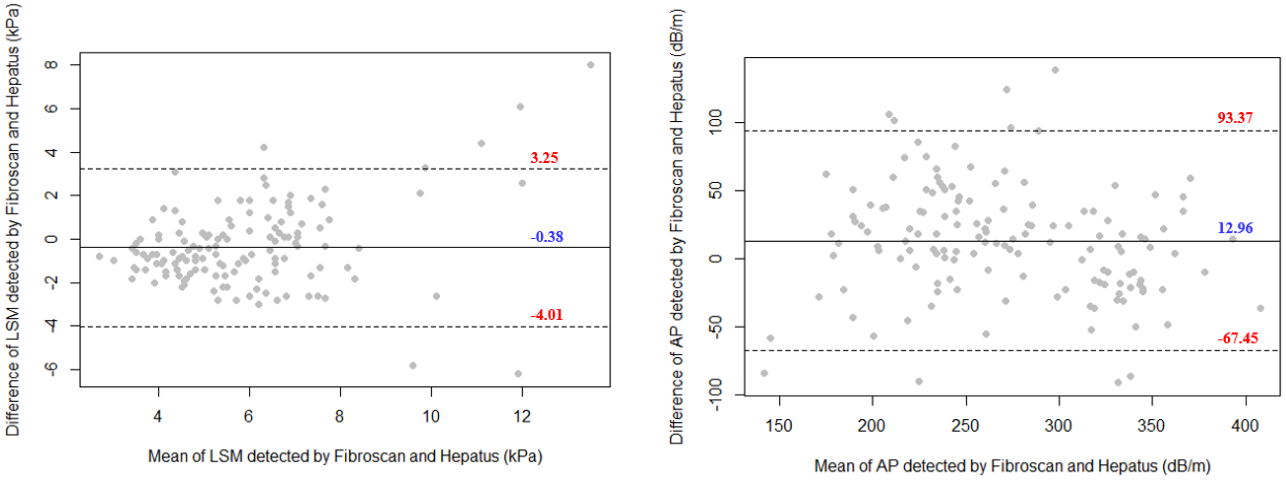
Abbreviations: BMI, body mass index; T2DM, type 2 diabetes mellitus.

RESULTS

Of the 172 participants initially recruited in this study, 149 were qualified to be included in performing TE examinations, and finally, we had 143 participants with valid detections of both two TE machines **(Figure 1).** The clinical and biochemical characteristics are shown in **Table 1 and Table 2**. There were 99 patients detected to have NAFLD by Fibroscan, while 44 were classified in the non-NAFLD group. The mean age of the participants was 42.7 years, with 76 (53.1%) being male. Notably, individuals in the NAFLD group were younger compared to those without NAFLD, exhibiting higher values for BMI, waist circumference, WHR, ALT, AST, GGT, and TG levels (all $P < 0.05$). Furthermore, a higher prevalence of obesity or abdominal obesity was observed in the NAFLD group compared to the non-NAFLD group.

The success rates for Fibroscan and Hepatus were 143/149 (96.0%) and 149/149 (100.0%), respectively. In the Fibroscan examinations, only 6 (4%) patients underwent assessments using the XL probe, while the remaining were conducted with the M probe. Bland–Altman analysis for LSM revealed a mean difference of -0.38 kPa between LSM values obtained by Fibroscan and Hepatus. The lower 95% limits of agreement (LoA) were -4.01 kPa, and the upper 95% LoA was 3.25 kPa (**Figure 3a**). For the attenuation parameter, Bland–Altman analysis demonstrated a mean difference of 12.96 dB/m between measurements obtained by Fibroscan and Hepatus. The lower 95% LoA was -67.45 dB/m, and the upper 95% LoA was 93.37 dB/m (**Figure 3b**).

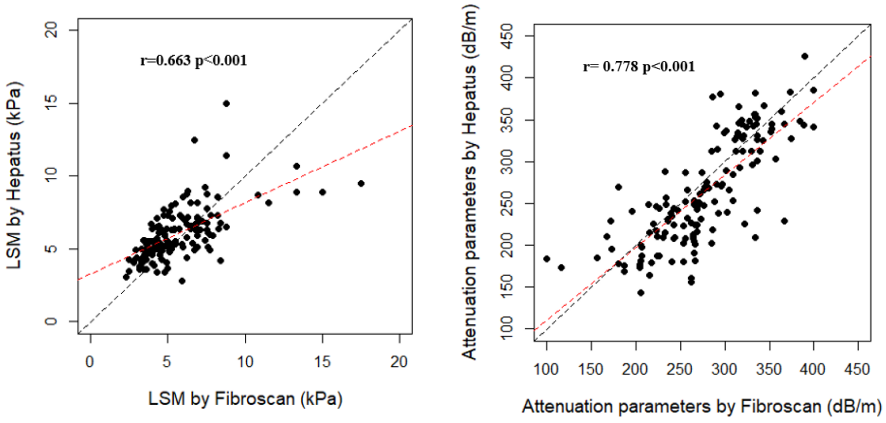
The correlation analysis of LSM and attenuation parameters between the two TE machines revealed a positive correlation. Specifically, LSM demonstrated a correlation coefficient (r) of 0.663 ($P < 0.001$, **Figure 4a**), and the attenuation parameter exhibited a correlation coefficient of 0.778 ($P < 0.001$, **Figure 4b**), indicating a significant positive correlation between Fibroscan and Hepatus measurements. In the comparison of detection results between Fibroscan and Hepatus (**Table 3**), it was observed that Hepatus tended to yield a higher LSM (Hepatus vs. Fibroscan: 6.04 vs. 5.66 kPa, $P = 0.016$). Conversely, the attenuation parameter obtained by Hepatus was lower than that obtained by Fibroscan (Hepatus vs. Fibroscan: 264 vs. 277 dB/m, $P < 0.001$). Additionally, the stability of multiple detection results from Hepatus was superior to that of Fibroscan. Specifically, both the IQR and IQR/median for LSM and attenuation parameters obtained using Hepatus were significantly lower compared to those obtained by Fibroscan (all $P < 0.05$). These findings highlight the nuanced differences and improved stability observed with Hepatus compared to Fibroscan.



3a) Liver stiffness measurements (LSM)　　3b) Attenuation parameter

Figure 3. Bland-Altman plot of the detection results of two TE machines.

(3a) Bland-Altman plot of liver stiffness index (LSM) obtained using Fibroscan and Hepatus, (3b) Bland-Altman plot of attenuation parameter obtained using Fibroscan and Hepatus.



4a) Liver stiffness measurement (LSM)　　4b) Attenuation parameter

Figure 4. Scatter plot of the detection values of two TE machines.

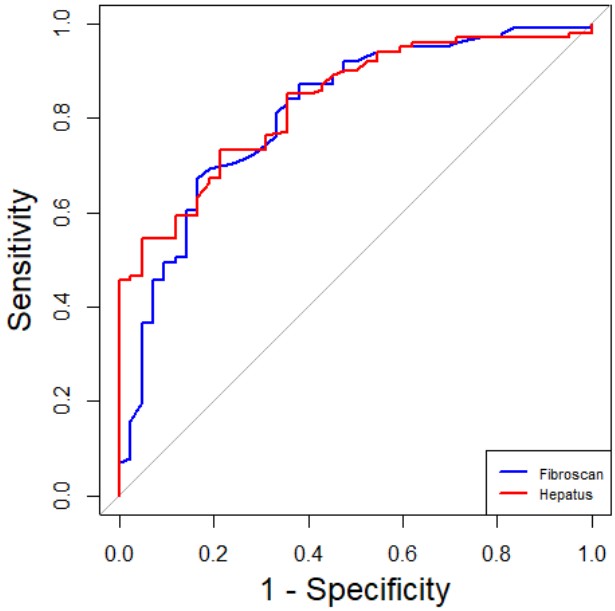
(4a) Scatter plot of liver stiffness index (LSM) obtained using Fibroscan and Hepatus, (4b) Scatter plot of attenuation parameter obtained using Fibroscan and Hepatus.

Table 3. Comparison of the detection results between Fibroscan and Hepatus (n = 143).

	Fibroscan	Hepatus	P
LSM			
Median, kPa	5.66 ± 2.34	6.04 ± 1.83	0.016
IQR, kPa	0.85 ± 0.58	0.60 ± 0.40	<0.001
IQR/Median, %	14.7 ± 6.4	10.0 ± 5.8	<0.001
Attenuation parameter			
Median, dB/m	277 ± 57.6	264 ± 64.2	<0.001
IQR, dB/m	25.9 ± 12.0	11.6 ± 7.99	<0.001
IQR/Median, %	10.0 ± 5.7	4.7 ± 3.9	<0.001

Abbreviations: LSM, liver stiffness measurement; IQR, interquartile range.

To determine the cut-off value of the attenuation parameter for predicting HSI-based NAFLD, ROC curve analysis was conducted (**Figure 5**). The area under the ROC curve was 0.811 for Fibroscan and 0.832 for Hepatus. The optimal cut-off values to predict NAFLD were 270 dB/m (with a sensitivity of 67.3% and specificity of 73.3%) and 240 dB/m (with a sensitivity of 83.3% and specificity of 78.5%) for Fibroscan and Hepatus, respectively.



	Fibroscan	Hepatus
The area under the ROC curve	0.811	0.832
Optimal cutoff value, dB/m	270	240
Sensitivity, %	67.3%	73.3%
Specificity, %	83.3%	78.5%

Figure 5. The receiver operating characteristic (ROC) curve of the two TE devices for detecting HSI-based NAFLD by attenuation parameter.

DISCUSSION

In this cross-sectional study involving 143 patients with metabolic dysregulation, we conducted a comprehensive comparison of detection results between Fibroscan and hepatitis in individuals at risk of NAFLD. Our analysis revealed that the detection values were strongly correlated for LSM and attenuation parameters, indicating the reliability and coherence of the measurements between the two TE devices. Furthermore, our study indicated that Hepatus exhibited superior stability in multiple detection results compared to Fibroscan. Importantly, our findings suggest that the diagnostic value of the two TE devices was equivalent in detecting HSI-based NAFLD. This emphasizes the potential of Hepatus as a comparable alternative to Fibroscan for NAFLD assessment, providing clinicians with valuable insights into liver health in patients with metabolic dysregulation.

NAFLD is recognized as a progressive condition, initially characterized as fatty liver with hepatic steatosis. When inflammation sets in, with or without fibrosis, it transitions to non-alcoholic steatohepatitis (NASH)(26). Both early liver steatosis and fibrosis in NAFLD are reversible, emphasizing the importance of early diagnosis for a positive impact on disease prognosis. Therefore, the primary focus for patients with NAFLD is the identification of simple steatosis, advanced liver fibrosis, and the distinction of NASH for appropriate management(4, 26). Historically, B-ultrasound was commonly employed for clinical diagnosis of fatty liver. However, its efficacy in detecting mild hepatic steatosis was often limited (27). Liver biopsy, considered the "golden standard," is invasive and associated with sampling errors and potential complications, including bleeding, hematoma, and pain, resulting in low patient acceptance (28), such as bleeding, hematoma, and pain, resulting in its low acceptance by patients. In response to these challenges, Fibroscan has emerged as a pivotal tool for detecting liver fibrosis and steatosis in chronic liver diseases(29, 30). Similar to Fibroscan, Hepatus represents an effective tool for liver TE examination.

Despite their similarities, no study has yet compared Fibroscan and Hepatus in measuring LSM and attenuation parameters for NAFLD. Ren et.al compared the efficiency of the two TE machines in detecting liver fibrosis(16) and liver steatosis(17) in patients with Chronic Hepatitis B and demonstrated Hepatus as an efficient, stable, and reliable TE tool for assessing liver fibrosis and steatosis. Our study demonstrated a robust correlation between Fibroscan and Hepatus in detecting LSM and attenuation parameters, showcasing the efficacy of Hepatus. Interestingly, we observed that the LSM values obtained with Hepatus were higher, which is consistent with the results in Chronic Hepatitis B patients(31), while the attenuation parameter values were lower than those with Fibroscan. This implies that, for clinical diagnosis, the cutoff values for the two devices may differ. While Fibroscan has established guidelines recommending corresponding cutoff values (32, 33), Hepatus may require exploration of specific cutoff values in participants with liver biopsy samples in the future. This highlights the importance of further research to establish device-specific diagnostic thresholds, enhancing the precision of NAFLD assessments.

In our study, both Fibroscan and Hepatus were employed to screen patients with metabolic dysregulation, and the AUC diagnostic performance of both attenuation parameters obtained by TE devices was found to be good (AUC > 0.7) in detecting HSI-based NAFLD. The use of the Hepatus for assessing NAFLD has not been reported. The optimal cut-off points for detecting HSI-based NAFLD for Hepatus and Fibroscan were determined to be 240 and 270 dB/m, respectively. To our knowledge, before our investigation, there had been no reported use of the Hepatus for evaluating this specific liver condition. This highlights the novelty of our approach and underscores the potential utility of Hepatus as a valuable tool in the realm of NAFLD diagnosis. Moreover, we determined optimal cut-off points for detecting HSI-based NAFLD using both Hepatus and Fibroscan. The identified thresholds provide practical benchmarks for clinicians in effectively identifying individuals at risk of NAFLD within the context of metabolic dysregulation.

Although Fibroscan has been widely used, it still has some limitations in the application of liver examination in obese patients. Fibroscan is a machine based on ultrasonic VCTE, which lacks 2D image guidance and requires probe replacement for patients with different body types. In contrast, Hepatus employs ViTE technology, guided by real-time images. This enables operators to selectively target sampling areas, mitigating interference from factors such as fat layers, large vessels, or lesions. The utilization of accurate and reliable positioning significantly reduces operational challenges, and enhances the success rate, accuracy, and repeatability of quantitative detection—all achieved without the need for probe replacement. Fibroscan's M probe is capable of measuring the subcutaneous area within the range of 2.5-6.5 cm. For obese patients, the XL probe is recommended, although the current clinical practice primarily utilizes the M probe. The accuracy of the XL probe warrants further evaluation (34). Conversely, Hepatus is equipped with a high-penetration mode in its probe, reducing the impact of BMI on measurements, especially beneficial for obese patients.

Several limitations need to be considered. Firstly, its single-center design may impact the generalizability of the findings. Conducting larger, multi-center studies could offer more comprehensive evidence and enhance the generalizability of the results. Further research is warranted to confirm the robustness of the observed associations across diverse populations. Secondly, the inability to evaluate the sensitivity and specificity of the two devices constitutes another limitation. This arises from the absence of gold standard data on liver stiffness and liver fat content in the current study. Future investigations with a more extensive dataset that includes a reliable gold standard for comparison would contribute to a more thorough understanding of the diagnostic accuracy of both Fibroscan and Hepatus.

CONCLUSION AND SUGGESTION

In summary, our study revealed a robust correlation in the detection results between Fibroscan and Hepatus in patients deemed "at-risk" of NAFLD, Hepatus demonstrated greater stability in its detection results. Importantly, the diagnostic performance of both TE devices was found to be equivalent in detecting HSI-based NAFLD. Our findings provided a more comprehensive understanding of the diagnostic capabilities of Fibroscan and Hepatus in the context of NAFLD assessment. It’s imperative to note that the results of this study, while promising, necessitate further validation in a larger sample size population, ideally incorporating liver biopsy examinations.

DATA AVAILABILITY STATEMENT

Data are available on reasonable request from the corresponding author.

ETHICS STATEMENT

The study complies with the Declaration of Helsinki. This study was approved by the Ethics Committee of the first affiliated hospital of Ningbo University (Approval No. 2019-R057), and written informed consent was obtained from all patients.

AUTHOR CONTRIBUTIONS

JHS and PPZ: analyze the data and write the manuscript. KW and MX: collect data. JS and LL: design the study, contribute to the writing, and review the manuscript.

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CONFLICT OF INTEREST

The authors have declared no conflict of interest.

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