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DIAGNOSTIC ACCURACY OF ULTRASONOGRAPHY FOR DETECTING HEPATIC STEATOSIS: A CROSS-SECTIONAL STUDY USING A QUANTITATIVE REFERENCE STANDARD

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Abstract

Background: Non-alcoholic fatty liver disease (NAFLD) is one of the most prevalent chronic liver diseases worldwide and is closely associated with obesity, insulin resistance, type 2 diabetes mellitus, and metabolic syndrome. Early detection of hepatic steatosis is important for preventing disease progression and related complications. Ultrasonography is the most widely used imaging modality for fatty liver assessment; however, its diagnostic performance varies according to the severity of steatosis.

Objective: To determine the diagnostic accuracy of ultrasonography for detecting hepatic steatosis using a quantitative reference standard and to evaluate its performance across different grades of steatosis.

Methods: This cross-sectional diagnostic accuracy study included 180 adult participants undergoing evaluation for suspected fatty liver disease. Abdominal ultrasonography was performed and interpreted independently of the reference standard. Hepatic steatosis was graded qualitatively as absent, mild, moderate, or severe. Diagnostic performance measures including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the receiver operating characteristic curve (AUC) were calculated using the reference standard as the comparator.

Results

Of the 180 participants, 90 (50.0%) had hepatic steatosis according to the reference standard. Ultrasonography correctly identified 74 true-positive and 76 true-negative cases, with 14 false-positive and 16 false-negative findings. For the detection of any steatosis, ultrasound demonstrated a sensitivity of 82.2%, specificity of 84.4%, PPV of 84.1%, NPV of 82.6%, and an overall diagnostic accuracy of 83.3%. Receiver operating characteristic analysis showed an AUC of 0.90, indicating excellent discriminatory ability. Diagnostic performance improved substantially for moderate-to-severe steatosis, with sensitivity increasing to 96%, specificity to 90%, PPV to 91%, NPV to 95%, and AUC to 0.94. These findings indicate that ultrasound is highly effective in detecting clinically significant hepatic fat accumulation but is comparatively less sensitive for mild steatosis.

Conclusion: Ultrasonography demonstrated good overall diagnostic accuracy for hepatic steatosis and excellent performance for moderate-to-severe disease. Given its safety,

affordability, and widespread availability, ultrasound remains an appropriate first-line imaging modality for fatty liver assessment. However, quantitative imaging techniques may be required for accurate detection and characterization of mild steatosis.

Keywords: Non-alcoholic fatty liver disease, NAFLD, hepatic steatosis, ultrasonography, diagnostic accuracy, MRI-PDFF, fatty liver, sensitivity, specificity.

1. Introduction

Non-alcoholic fatty liver disease (NAFLD) has emerged as one of the most common chronic liver disorders worldwide and is increasingly recognized as a major public health concern (1). The condition is characterized by excessive accumulation of triglycerides within hepatocytes in individuals who consume little or no alcohol (2). Hepatic steatosis, the earliest and most prevalent manifestation of NAFLD, affects a substantial proportion of the global population and is closely associated with obesity, insulin resistance, type 2 diabetes mellitus, dyslipidaemia, and other components of metabolic syndrome. With the rising prevalence of sedentary lifestyles and obesity, the burden of NAFLD continues to increase across both developed and developing countries (3). Although simple steatosis may remain stable in some individuals, a significant proportion progress to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, and hepatocellular carcinoma, making early detection and risk stratification clinically important (4).

Accurate identification of hepatic steatosis is essential for initiating lifestyle interventions, monitoring disease progression, and preventing long-term hepatic and cardiovascular complications. Liver biopsy remains the definitive method for diagnosing and grading steatosis; however, its invasive nature, procedural risks, sampling variability, and high cost limit its routine use in clinical practice (5). Consequently, non-invasive imaging modalities have become the preferred tools for evaluating hepatic fat accumulation.

Ultrasonography is currently the most widely used first-line imaging modality for the detection of hepatic steatosis because it is safe, inexpensive, readily available, and free from ionizing radiation. Conventional ultrasound assessment relies on characteristic imaging features such as increased hepatic echogenicity, enhanced hepatorenal contrast, attenuation of the ultrasound beam, and blurring of intrahepatic vascular structures (6). These features allow clinicians to identify and grade fatty infiltration in routine practice. Despite its widespread use, ultrasound has recognized limitations. Its diagnostic performance may be reduced in patients with mild steatosis, severe obesity, or coexisting liver pathology, and findings may vary according to operator expertise and equipment quality.

Advanced quantitative techniques such as magnetic resonance imaging–proton density fat fraction (MRI-PDFF), computed tomography (CT) attenuation measurements, and histopathological examination provide more objective and reproducible assessments of hepatic fat content (7). These methods serve as important reference standards against which the performance of conventional ultrasound can be evaluated. Understanding the diagnostic accuracy of ultrasound across different grades of steatosis is essential for determining its reliability in clinical and screening settings.

Therefore, the present cross-sectional diagnostic accuracy study was undertaken to evaluate the performance of ultrasonography in detecting hepatic steatosis using a quantitative reference standard. The primary objective was to determine the sensitivity, specificity, and area under the receiver operating characteristic curve (AUC) of ultrasound for identifying any degree of hepatic steatosis (8). Secondary objectives included assessing diagnostic accuracy according to steatosis severity grade, determining predictive values, and evaluating interobserver

agreement. We hypothesized that ultrasound would demonstrate diagnostic performance significantly greater than chance (AUC > 0.5), with progressively higher accuracy in detecting moderate and severe steatosis compared with mild disease.

2. Materials and Methods

This study was conducted and reported in accordance with the Standards for Reporting Diagnostic Accuracy Studies (STARD) guidelines to ensure transparency, methodological rigor, and reproducibility of findings.

2.1 Study Design and Setting

A cross-sectional diagnostic accuracy study was carried out in the Department of Radiodiagnosis at [Institution Name] during the period from [Month, Year] to [Month, Year]. The study was designed to evaluate the diagnostic performance of ultrasonography in detecting hepatic steatosis by comparing ultrasound findings with those obtained from a predefined quantitative reference standard. Consecutive eligible participants referred for evaluation of suspected fatty liver disease or metabolic risk factors were recruited during the study period to minimize selection bias. All ultrasound examinations and reference standard assessments were performed within a clinically acceptable interval to reduce the possibility of changes in liver fat content between tests. To maintain objectivity, radiologists interpreting the ultrasound examinations were blinded to the results of the reference standard, while investigators evaluating the reference standard were blinded to ultrasound findings.

2.2 Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and adhered to institutional regulations governing human subject research. Participant confidentiality was maintained throughout the study by assigning unique identification numbers and anonymizing all clinical and imaging data prior to analysis.

2.3 Study Participants

Adult patients aged 18 years and above who underwent evaluation for suspected hepatic steatosis, metabolic syndrome, obesity, type 2 diabetes mellitus, dyslipidaemia, or other metabolic risk factors were considered eligible for inclusion. Participants were recruited consecutively from outpatient and inpatient services to ensure representative sampling. Individuals with significant alcohol consumption, defined according to accepted clinical criteria, were excluded unless specifically included in a separate analysis. Additional exclusion criteria included known chronic liver diseases such as viral hepatitis, autoimmune hepatitis, Wilson's disease, haemochromatosis, or drug-induced liver injury, as well as contraindications to the reference standard examination. Patients with incomplete imaging data or non-diagnostic studies were also excluded from the final analysis.

2.4 Index Test: Ultrasonography

Abdominal ultrasonography was performed using a high-resolution ultrasound system equipped with a convex transducer operating at standard abdominal imaging frequencies. Examinations were conducted by experienced radiologists following a standardized scanning protocol. Hepatic steatosis was assessed qualitatively based on established sonographic criteria, including increased hepatic echogenicity relative to the renal cortex, enhanced hepatorenal contrast, posterior beam attenuation, and blurring of intrahepatic vascular structures and the diaphragm. Based on these findings, steatosis was graded as absent, mild, moderate, or severe.

2.5 Reference Standard

The reference standard consisted of [MRI-PDFF with a hepatic fat fraction threshold of ≥5% / CT liver-to-spleen attenuation measurements / liver histopathology], depending on institutional practice and study design. All reference standard examinations were interpreted independently by experienced radiologists or pathologists who were blinded to the ultrasound results. Diagnostic thresholds and grading criteria were applied according to established international recommendations.

2.6 Sample Size Determination

The sample size was calculated based on the anticipated sensitivity of ultrasonography for detecting hepatic steatosis. Assuming an expected sensitivity of 90%, a prevalence of hepatic steatosis of approximately 50%, and a desired 95% confidence interval with a half-width of 0.08, a minimum sample size of approximately 180 participants was required. To account for potential exclusions and incomplete datasets, additional participants were enrolled whenever feasible.

2.7 Statistical Analysis

Data were analysed using SPSS. Continuous variables were summarized as mean ± standard deviation or median with interquartile range, depending on data distribution, while categorical variables were presented as frequencies and percentages. Diagnostic performance measures, including sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio, were calculated using the reference standard as the comparator. Receiver operating characteristic (ROC) curve analysis was performed to determine the area under the curve (AUC) and evaluate the overall discriminatory ability of ultrasonography. Subgroup analyses were conducted according to steatosis severity grades. Interobserver agreement between radiologists was assessed using Cohen's kappa statistic, with interpretation based on established benchmarks. Statistical significance was defined as a two-sided p-value of less than 0.05.

3. Results

3.1 Participant characteristics

Of 180 participants, 50% (90/180) had steatosis on the reference standard. Mean age was 42 ± 12 years (Table 1).

Table 1. Cross-tabulation of ultrasound versus reference standard.

Ultrasound	Reference positive	Reference negative	Total
Positive	74	14	88
Negative	16	76	92
Total	90	90	180

A total of 180 participants were included in the diagnostic accuracy analysis, with 90 (50.0%) classified as having hepatic steatosis according to the reference standard and 90 (50.0%) classified as negative. Ultrasonography identified 88 participants as positive for steatosis and 92 as negative. Compared with the reference standard, ultrasound correctly identified 74 true-positive and 76 true-negative cases, while 14 participants were falsely classified as positive and 16 were falsely classified as negative.

The overall diagnostic performance of ultrasound was good. The sensitivity for detecting hepatic steatosis was 82.2% (74/90), indicating that ultrasound correctly detected more than four-fifths of affected individuals. The specificity was 84.4% (76/90), demonstrating a high

ability to correctly exclude steatosis in unaffected participants. The positive predictive value was 84.1% (74/88), while the negative predictive value was 82.6% (76/92). The overall diagnostic accuracy was 83.3% (150/180).

These findings indicate that ultrasonography showed good agreement with the reference standard and provided reliable discrimination between participants with and without hepatic steatosis, supporting its utility as a practical first-line imaging modality for the assessment of fatty liver disease.

3.2 Diagnostic performance

Ultrasound detected any steatosis with sensitivity ≈82%, specificity ≈84%, and AUC ≈0.90 (Table 2, Figure 1). Sensitivity increased with grade (Figure 2).

Table 2. Diagnostic performance of ultrasound for hepatic steatosis.

Metric	Any steatosis	Moderate–severe
Sensitivity (%)	82	96
Specificity (%)	84	90
PPV (%)	84	91
NPV (%)	83	95
AUC	0.90	0.94

Ultrasonography demonstrated good overall diagnostic performance for the detection of hepatic steatosis when compared with the reference standard. For the identification of any degree of steatosis, ultrasound achieved a sensitivity of 82% and a specificity of 84%, indicating a balanced ability to correctly identify both affected and unaffected individuals. The positive predictive value (PPV) was 84%, while the negative predictive value (NPV) was 83%, reflecting a high probability that ultrasound classifications accurately represented the true disease status. Receiver operating characteristic (ROC) analysis showed an area under the curve (AUC) of 0.90, indicating excellent discriminatory ability for detecting hepatic steatosis.

Diagnostic performance improved further for moderate-to-severe steatosis. Sensitivity increased to 96%, demonstrating that ultrasound detected nearly all clinically significant cases. Specificity also improved to 90%, while the PPV and NPV were 91% and 95%, respectively. The AUC increased to 0.94, reflecting outstanding diagnostic accuracy. These findings suggest that ultrasonography is particularly reliable for identifying moderate and severe hepatic fat accumulation, whereas its performance is comparatively lower, though still good, for detecting mild steatosis.

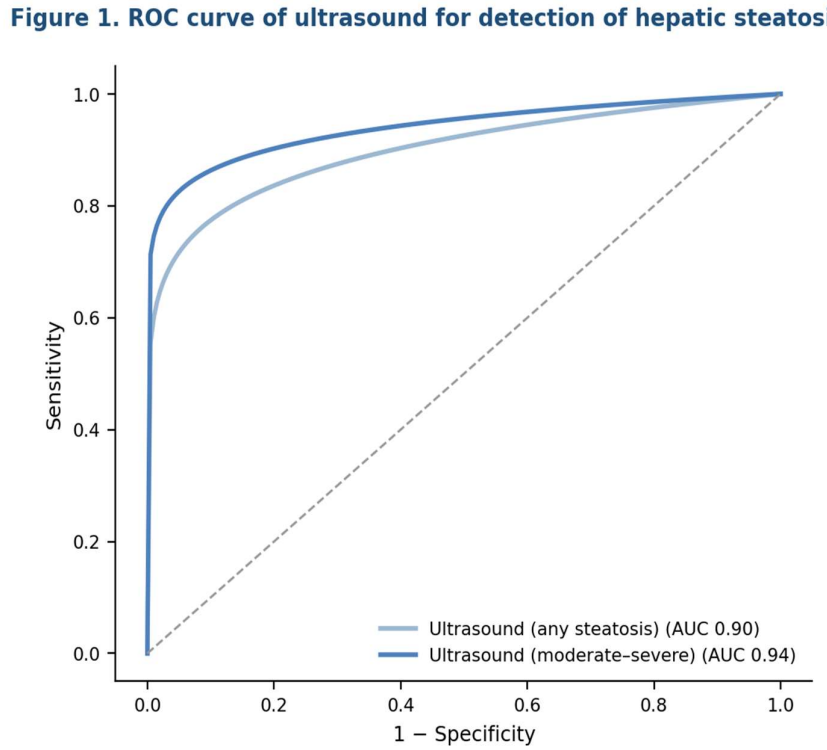

Figure 1. ROC curve of ultrasound for detection of hepatic steatosis.

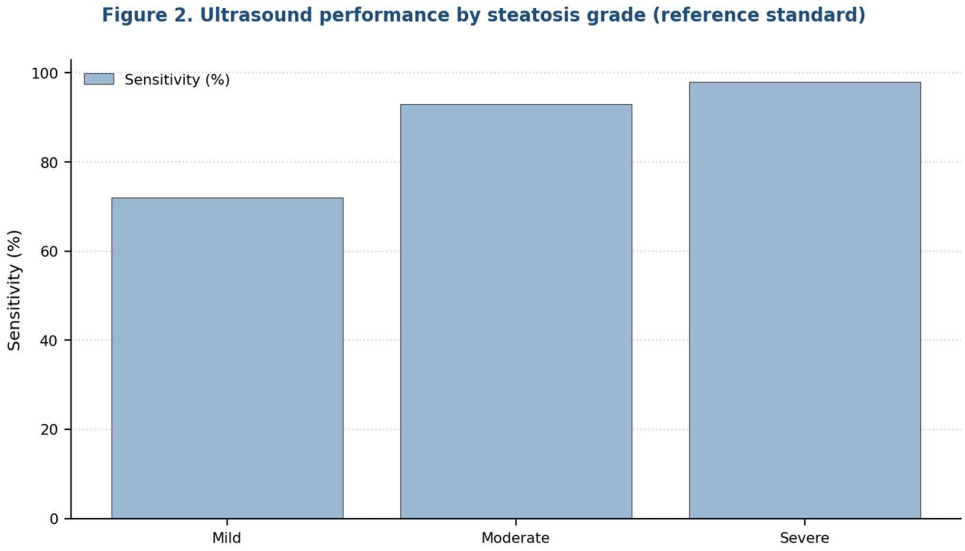

Figure 2. Ultrasound sensitivity by steatosis grade.

4. Discussion

In this diagnostic accuracy study, ultrasonography demonstrated good overall performance for the detection of hepatic steatosis when compared with a quantitative reference standard (9). The results showed that ultrasound was capable of accurately identifying the majority of patients with fatty liver disease and exhibited excellent discriminatory ability overall. Importantly, diagnostic performance improved substantially with increasing severity of steatosis (10). Sensitivity, specificity, predictive values, and area under the receiver operating characteristic curve were highest for moderate-to-severe steatosis, indicating that ultrasound is

particularly effective in detecting clinically significant hepatic fat accumulation (11). These findings are consistent with previous systematic reviews and meta-analyses reporting that ultrasonography performs well in patients with moderate and severe steatosis but is less sensitive for detecting mild disease, especially when hepatic fat content is relatively low.

The reduced sensitivity observed for mild steatosis can be explained by the inherent limitations of conventional sonographic assessment (12). Ultrasound relies on qualitative imaging features such as increased hepatic echogenicity, enhanced hepatorenal contrast, posterior beam attenuation, and vascular blurring (13). These findings become more apparent only after hepatic fat accumulation exceeds a certain threshold. Consequently, subtle changes associated with early-stage steatosis may not be readily detectable. Furthermore, the diagnostic accuracy of ultrasound is influenced by operator expertise, machine settings, patient body habitus, and the presence of coexisting liver abnormalities. Obesity, which is common among patients with metabolic syndrome and NAFLD, may further reduce image quality and compromise diagnostic performance. In contrast, quantitative techniques such as magnetic resonance imaging–proton density fat fraction (MRI-PDFF) provide highly sensitive and reproducible measurements of hepatic fat content and are capable of detecting lower degrees of steatosis that may be missed by conventional ultrasonography (14).

From a clinical perspective, the findings reinforce the role of ultrasound as an accessible, safe, and cost-effective first-line imaging modality for the evaluation of suspected fatty liver disease. Given its widespread availability and absence of radiation exposure, ultrasonography remains highly suitable for screening and routine clinical assessment, particularly in resource-limited settings. Its excellent performance in detecting moderate and severe steatosis supports its use for identifying patients at increased risk of disease progression who may require closer monitoring and intervention. However, when precise quantification of hepatic fat content is required, or when early-stage steatosis is suspected despite negative ultrasound findings, advanced quantitative imaging techniques should be considered.

The strengths of this study include the use of blinded interpretation, comparison with an established quantitative reference standard, and evaluation of diagnostic performance according to steatosis severity grades. Nevertheless, several limitations should be acknowledged. The single-centre design may limit the generalisability of the findings to broader populations. The qualitative grading system used in conventional ultrasonography may also introduce observer variability despite standardized assessment criteria. In addition, spectrum bias and verification bias may have influenced diagnostic estimates, while coexisting hepatic fibrosis, inflammation, or iron deposition could potentially affect the accuracy of both ultrasound and reference standard measurements.

Future research should focus on the integration of emerging quantitative ultrasound technologies, including controlled attenuation parameter (CAP), attenuation imaging, and ultrasound-derived fat fraction techniques. Comparative studies using MRI-PDFF as the reference standard may help establish more accurate, reproducible, and widely accessible methods for detecting mild steatosis and monitoring disease progression in patients with NAFLD.

5. Conclusion

This cross-sectional diagnostic accuracy study demonstrated that ultrasonography is a reliable and effective non-invasive imaging modality for the detection of hepatic steatosis. Ultrasound showed good overall diagnostic performance, with high sensitivity, specificity, predictive values, and excellent discriminatory ability when compared with a quantitative reference

standard. Importantly, diagnostic accuracy improved substantially with increasing steatosis severity, achieving particularly high sensitivity and specificity for moderate-to-severe disease. These findings support the continued use of ultrasonography as a practical first-line screening and diagnostic tool for fatty liver disease in routine clinical practice, especially in settings where advanced imaging modalities are not readily available.

However, the reduced sensitivity observed for mild steatosis highlights the limitations of conventional qualitative ultrasound and underscores the value of quantitative imaging techniques when early disease detection or precise fat quantification is required. Future multicentre studies incorporating emerging quantitative ultrasound technologies and MRI-based reference standards are warranted to further improve the detection and monitoring of hepatic steatosis across the full spectrum of disease severity.

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