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DIAGNOSTIC ACCURACY OF ULTRASONOGRAPHY AND FIBROSCAN CONTROLLED ATTENUATION PARAMETER IN DIAGNOSING NON-ALCOHOLIC FATTY LIVER DISEASE, KEEPING NON-CONTRAST COMPUTED TOMOGRAPHY AS REFERENCE STANDARD

Dr. Kanwal Shan[*1], Dr. Tahir Malik[2], Dr. Kiran Shan[3], Dr. Usman Farooq[4], Dr. Rukhsar Butt[5], Dr. Bakht Bilal[6]

*[*1,4,5,6](MBBS), Postgraduate Resident (FCPS) Diagnostic Radiology, Pakistan Kidney and Liver Institute and Research Centre Lahore.*
[2](MBBS, FCPS), Consultant Diagnostic Radiology, Pakistan Kidney and Liver Institute and Research Centre Lahore.
[3](MBBS), Registrar Anesthesia, Department of Anesthesia and Critical Care, Bahria Orchard Hospital, Lahore.

*[*1]kanwalshan15@gmail.com, [2]tahirmalik@gmail.com, [3]kiranshaan524@gmail.com, [4]drusmanfarooq1058@gmail.com, [5]rukhsar.butt7799@yahoo.com, [6]bilal94x@gmail.com

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Corresponding Author: *
Dr. Kanwal Shan

Abstract

OBJECTIVE: *To determine the diagnostic accuracy of hepatic ultrasonography and Fibroscan Controlled Attenuation Parameter in detecting the presence or absence of hepatic steatosis by taking Non-Contrast Computed Tomography of Abdomen as reference standard.*

MATERIAL AND METHODS: *Study Setting was Radiology Department, Pakistan Kidney and Liver Institute and Research Centre (PKLI&RC). Study Design was Cross Sectional Study with study duration of 6 months. Sample Size (n) of 165 patients has been calculated with 95% confidence level taking prevalence of NAFLD 68.3% (4). Non-Probability consecutive sampling technique was used. Inclusion criteria included patients of both genders, having age between 15-60 years, BMI between 17.5 to 30kg/m2, including patients referred to the radiology department for suspected diagnosis of fatty liver. Data analysis was done using SPSS 20.0. The Chi-square test was applied with p-value S≤ 0.05 considered as significant.*

RESULTS: *The study included 165 individuals, with a **slightly higher male representation (55.2%)**. The majority of participants were within the **31–60-year** age group, indicating a population vulnerable to metabolic liver disorders. FibroScan Controlled Attenuation Parameter (CAP) demonstrated slightly superior diagnostic performance, with a **sensitivity of 90.8%**and **specificity of 91.0%**. Its **PPV (93.7%)** and **NPV (87.1%)** were both high, indicating a reliable tool for non-invasive detection of hepatic steatosis. CAP's performance suggests it may be particularly useful in borderline or early-stage cases that might be missed by ultrasonography.*

CONCLUSION: *Both ultrasonography and FibroScan CAP showed strong diagnostic capabilities in detecting NAFLD when compared to non-contrast CT. While USG remains accessible and cost-effective, CAP offers slightly better*

sensitivity and NPV, making it a valuable alternative in clinical settings requiring greater diagnostic precision.

INTRODUCTION

Non-alcoholic fatty liver disease is defined as the pathological presence of hepatic steatosis with more than 5 % fat in the liver, in the form of triacylglycerol rich macro vesicular lipid droplets within the hepatocytes in the absence of any liver injury, alcohol usage, infection or inflammation (l). Its prevalence is variable and ranges from 20-40 % in general population (2). Risk factors for development of NAFLD include obesity, diabetes, hypertension and dyslipidemias. It ranges from benign conditions like mild hepatic steatosis to advanced stages including non-alcoholic steatohepatitis (NASH) to hepatic cirrhosis and hepatocellular carcinoma, (3) therefore, early diagnosis and management is of paramount importance to prevent disease progression. High caloric diet and sedentary lifestyle has a role in the development and progression of fatty liver disease however, it's considered a benign condition and is reversible by dietary and lifestyle modifications and by treatment of underlying metabolic and systemic diseases.(3)

Histopathology is the gold standard for the diagnosis and evaluation of Non-alcoholic fatty liver; however, biopsy is an invasive procedure and is limited by its lack of availability at all hospitals, cost effectiveness, sampling error and post procedure complications such as pain and bleeding(4). Various noninvasive techniques are being considered for hepatic steatosis assessment which are readily available, pain free and cost effective including ultrasonography, Fibroscan, Computed Tomography and Magnetic Resonance imaging.

Conventional B mode ultrasonography is the most widely used, safe, non-invasive, and highly accessible technique to diagnose and grade hepatic steatosis by comparing hepatic echogenicity with that of hepatic vasculature, spleen, kidney and diaphragm(5). A study shows hepatic ultrasound sensitivity and specificity of 66.7% and 83.5% respectively (5). However, it has a few limitations including being operator dependent, highly subjective in natureand the inter-observer disagreement(4).

The controlled attenuation parameter (CAP) is recently introduced as a new parameter for diagnosing NAFLD by measuring ultrasonic attenuation in the liver using ultrasonic signals acquired by FibroScan (6). The CAP score is measured in decibels per meter (DB/m) and ranges from 100-400. As per a recent meta-analysis, Fibroscan CAP has sensitivity and specificity values of 85% and 74% respectively for differentiating between normal liver and grade-I hepatic steatosis (7).

Unenhanced abdominal CT scan is known for accurately detecting NAFLD of macro vesicular steatosis of 30% or greater(4), having reported specificity and sensitivity of 100% (95% CI: 670-100) and 95% (95% CI: 90-98), respectively, at a cutoff hepatic attenuation of 58 HU and 73% (95% CI: 43-91) and 100% (95% CI:97-100), respectively, at a cutoff of 42 HU 2. The measurable Hounsfield Units (HU) Values of a normal liver range between the 50 to 60 HU 9.

This study aims to assess the accuracy of ultrasonography and Fibro Scan in diagnosing NAFLD keeping non-contrast CT scan as reference standard. This will add to the patient benefit in determining the better, reliable, and more cost-effective modality for early and accurate diagnosis of NAFLD without the need to proceed for more expensive, invasive, and high radiation imaging techniques, thus preventing excessive radiation exposure and wastage of resources, especially in liver donors where even mild hepatic steatosis is a concern for donor rejection. There is a lot of international data available on this subject, however, limited data on such comparative studies are available for Pakistani population.

Non-contrast CT abdomen is used as a reference standard due to it being readily available and frequently performed as compared to infrequent liver biopsies, its invasive nature, cost effectiveness and complications, which makes it one of the limitations of this study. To counter the limitation of non-contrast CT abdomen in falsely detecting hepatic steatosis in pathological conditions like hepatic edema and Wilson's disease, appropriate inclusion and exclusion criteria are used.

MATERIAL AND METHODS

Study Setting was Radiology Department, Pakistan Kidney and Liver Institute and Research Centre (PKLI& RC). Study Duration was 6 months after the approval of synopsis. Study Design was Cross Sectional Study. Sample Size: sample size (n) of 165 patients has been calculated with 95% confidence level taking prevalence of NAFLD 68.3%(4), Ultrasound sensitivity and specificity of 83.5% and 66.7% (4) and margin of error 13% in predicting presence of Non-Alcoholic Fatty Liver Diseases. Non-Probability consecutive sampling technique was used. Sample selection included inclusion and exclusion criteria. Inclusion criteria included patients of both genders, patients of age 15-60 years, BMI between 17.5 to 30kg/m2 and patients referred to the radiology department for suspected diagnosis of fatty liver. Exclusion criteria included patients with presence of liver diseases other than NAFLD, for example; known cases of acute viral or autoimmune hepatitis / Wilsons disease etc, patients having a history of alcohol consumption and pregnant patients. Data Collection procedure was done after taking written informed consent from 165 patients after the approval of the ethical research committee. Relevant history was taken, and BMI was calculated to apply inclusion and exclusion criteria. On the patients fulfilling the criteria, grey-scale upper abdominal ultrasonography was performed for the assessment of hepatic steatosis through ultrasound machine GE LOGIC S8 with curvilinear probe 3.5- 6.5 MHz. Fibroscan of the same patient was then performed by placing M probe of Echosense fibroscan 502 perpendicular to the body of a patient who had been fasting for 4 hours (8) and the CAP value was determined.

Lastly, non-contrast CT scan abdomen of each patient was performed on a 128 slice CT scanner (Revolution Evo, GE) using detector collimation of 5mm with the table speed/rotation of
15 mm/ 0.8 sec and an image thickness of 5mm. Average attenuation of liver parenchyma was calculated by placing the circular region of interest of at least 1 cm^2 area at multiple places in the liver segments and splenic attenuation was measured by placing the circular region of interest at its upper, middle, and lower poles and hepatic steatosis was assessed (14). All this information was recorded in the pre-designed proforma. The ultrasound, fibroscan and Non-contrast CT were performed by trained technicians and were interpreted and reported by radiologists, with at least 3 years of experience who were blinded to the findings of other modalities to avoid bias. Data analysis was done using SPSS 20.0 to analyze the collected data. Mean and standard deviation were determined for the quantitative data like age and BMI. Qualitative variables e.g, gender, presence of hepatic steatosis on ultrasonography, fibroscan and computed tomography were presented in the form of frequency and percentages. Frequency table of 2 x 2 was used to calculate sensitivity, specificity, positive predictive value, and negative predictive values of abdominal ultrasound and fibroscan separately in detecting NAFLD using data of non-contrast CT abdomen as reference standard.The Chi-square test was applied with p-value S≤0.05 considered as significant.

RESULTS

A total of 165 patients participated in the study.

Table 1: Baseline Demographic Characteristics of Study Participants

Variable	Category	Frequency (n)	Percentage (%)
Gender	Male	91	55.2%
	Female	74	44.8%
Age (years)	15–30	38	23.0%
	31–45	64	38.8%
	46–60	63	38.2%
BMI (kg/m²)	17.5–22.9	31	18.8%
	23–25.9	48	29.1%
	26–30	86	52.1%

The study included 165 individuals, with a slightly higher male representation (55.2%). The majority of participants were within the 31–60 year age group, indicating a population vulnerable to metabolic liver disorders. Over half of the participants (52.1%) had a BMI between 26 and 30 kg/m², suggesting a substantial prevalence of overweight individuals,consistent with increased risk for hepatic steatosis. The mean age of the study participants was 40.16 years with standard deviation of 11.69 years, and the mean BMI was 25.5 kg/m²with standard deviation of 2.98 kg/m².

Table 2: Detection of Hepatic Steatosis by Imaging Modality

Imaging Modality	Steatosis Present (n)	Steatosis Absent (n)	Total (n)
Non-contrast CT	98	67	165
Ultrasonography (USG)	91	74	165
FibroScan CAP	95	70	165

Out of 165 patients, CT identified hepatic steatosis in 98 patients (59.4%), establishing the reference diagnosis. Ultrasonography detected steatosis in 91 patients, while FibroScan CAP identified 95 cases, both showing high agreement with CT. These results underscore the capability of non-invasive methods in detecting fatty liver, with CAP slightly outperforming USG in total detections.

Table 3: Diagnostic Accuracy of Ultrasonography (USG) Compared to CT

	CT: Steatosis Present	CT: Steatosis Absent	Total
USG: Steatosis Present	86 (True Positives)	5 (False Positives)	91
USG: Steatosis Absent	12 (False Negatives)	62 (True Negatives)	74
Total	98	67	165

Sensitivity: 87.8%, Specificity: 92.5%, Positive Predictive Value (PPV): 94.5%, Negative Predictive Value (NPV): 83.8%. When compared against the gold standard CT, ultrasonography demonstrated a sensitivity of 87.8% and specificity of 92.5%, indicating it was both effective at detecting steatosis and correctly excluding healthy livers. Its PPV of 94.5% suggests a high accuracy in positive diagnoses, while the NPV of 83.8% implies a modest chance of false negatives.

Table 4: Diagnostic Accuracy of FibroScan CAP Compared to CT

	CT: Steatosis Present	CT: Steatosis Absent	Total
CAP: Steatosis Present	89 (True Positives)	6 (False Positives)	95
CAP: Steatosis Absent	9 (False Negatives)	61 (True Negatives)	70
Total	98	67	165

Sensitivity: 90.8%, Specificity: 91.0%, Positive Predictive Value (PPV): 93.7%, Negative Predictive Value (NPV): 87.1%. FibroScan CAP demonstrated slightly superior diagnostic performance, with a sensitivity of 90.8% and specificity of 91.0%. Its PPV (93.7%)and NPV (87.1%) were both high, indicating a reliable tool for non-invasive detection of hepatic steatosis. CAP's performance suggests it may be particularly useful in borderline or early-stage cases that might be missed by ultrasonography. Both ultrasonography and FibroScan CAP showed strong diagnostic capabilities in detecting NAFLD when compared to non-contrast CT. While USG remains accessible and cost-effective, CAP offers slightly better sensitivity and NPV, making it a valuable alternative in clinical settings requiring greater diagnostic precision.

To asses the statistical association between imaging modalities and the reference standard, chi square test of independence was applied to the 2 x 2 contingency tables. For ultrasound, the chi-square value of 100.50 with p-value of < 0.001 was observed. This highly

significant result indicates a strong association between ultrasound and the reference standard. Similarly, for fibroscan compared with CT scan, chi-square value of 105.8 with p-value of <0.001 was observed, demonstrating a statistically significant association between fibroscan CAP and CT reference standard.

DISCUSSION

Non-alcoholic fatty liver disease (NAFLD) has become one of the most common chronic liver disorders globally, often linked to increasing rates of obesity, type 2 diabetes mellitus, and metabolic syndrome. The early identification and accurate diagnosis of NAFLD are crucial due to its potential progression to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, and hepatocellular carcinoma if left undiagnosed and untreated [1]. In this study, we compared the diagnostic accuracy of ultrasonography and FibroScan controlled attenuation parameter (CAP) against non-contrast computed tomography (CT), which served as the reference standard.

Our findings revealed that ultrasonography demonstrated a high sensitivity of 87.8% and specificity of 92.5%, with a positive predictive value (PPV) of 94.5% and a negative predictive value (NPV) of 83.8%. These results suggest that ultrasound is a highly effective tool for detecting hepatic steatosis and accurately ruling out healthy liver tissue when compared to non-contrast CT. These values are consistent with prior studies which report sensitivity and specificity ranges for ultrasound in detecting NAFLD between 60–94% and 66–97%, respectively [2,3]. The accuracy seen in our cohort may be attributed to the use of high-resolution imaging equipment and the interpretation by experienced radiologists, who were blinded to other findings to prevent bias.

FibroScan CAP, while not reported with exact numeric values in this paper, is well-documented in the literature for its ability to detect steatosis with moderate to high accuracy, typically showing sensitivity ranging from 70% to 90% and specificity from 80% to 90% depending on the cut-off values used and patient populations [4,5]. CAP technology, which quantifies liver fat using ultrasound attenuation, offers the advantage of operator independence and reproducibility, and is particularly useful for quantifying the severity of steatosis non-invasively.

The higher diagnostic performance of ultrasonography in our study may also be related to the patient selection criteria. By restricting the sample to individuals with BMI between 17.5 and 30 kg/m², we potentially excluded the confounding influence of obesity-related technical limitations commonly encountered with ultrasound. It is well known that ultrasonography's effectiveness diminishes with increasing adiposity due to poor acoustic penetration [6]. Moreover, the use of experienced radiologists and standardization of technique using a GE LOGIC S8 system likely improved diagnostic performance and inter-observer reliability.

Several studies have emphasized the role of CAP in quantifying steatosis, with diagnostic thresholds being established for mild (S1), moderate (S2), and severe (S3) steatosis [7,8]. However, CAP readings can be affected by several factors, including increased liver stiffness, body habitus, and fasting state, all of which may introduce variability into the results [9]. In contrast, ultrasonography, although more subjective and qualitative, is still widely favored as a frontline imaging modality due to its cost-effectiveness, widespread availability, and lack of radiation exposure [10].

Non-contrast CT, though not recommended for routine NAFLD screening due to radiation risks, served as a reliable reference standard in our study. It provides a validated, quantitative approach to assess hepatic fat based on liver-spleen attenuation differences and has been used in multiple studies as a non-invasive surrogate for hepatic steatosis [11]. This method is particularly useful in a research context due to its objectivity and high spatial resolution, although its ability to differentiate between simple steatosis and NASH is limited [12].

Both ultrasonography and FibroScan CAP showed strong diagnostic capabilities in detecting NAFLD when compared to non-contrast CT. While USG remains accessible and cost-effective, CAP offers slightly better sensitivity and NPV, making it a valuable alternative in clinical settings requiring greater diagnostic precision. In settings like Pakistan, where healthcare resources may be constrained, the reliance on ultrasonography offers an efficient and

reliable diagnostic alternative for initial screening and management of NAFLD [13].

Nonetheless, there are notable limitations in our study. Being a cross-sectional analysis, we were unable to assess disease progression or temporal associations. Additionally, while non-contrast CT served as the reference standard, histopathological confirmation through liver biopsy remains the definitive diagnostic method for NAFLD, especially in distinguishing steatosis from steatohepatitis or fibrosis [14]. However, due to its invasive nature and associated risks, biopsy is impractical for large-scale studies or routine clinical evaluations. Furthermore, we excluded individuals with extreme BMI values and certain liver comorbidities, which may limit the generalizability of our results.

Future studies may benefit from incorporating a larger, more diverse patient population, including those with morbid obesity and metabolic comorbidities, to evaluate the consistency of imaging results across a broader spectrum. Additionally, combining modalities—such as using CAP for quantification and ultrasound for anatomical assessment—may enhance diagnostic confidence. The emerging use of artificial intelligence and machine learning for image interpretation could also standardize assessments and reduce observer variability in ultrasonography [15].

In conclusion, our study reaffirms the high diagnostic accuracy of ultrasonography for detecting NAFLD, particularly in patients with average BMI, and supports its use as a cost-effective first-line imaging tool. While FibroScan CAP offers quantitative advantages and objectivity, its limited availability and cost implications may limit its widespread use in resource-limited settings. Non-contrast CT remains a valuable research reference but is less practical for routine use. Taken together, these findings contribute to a growing body of evidence guiding optimal imaging strategies for NAFLD diagnosis in clinical and resource-variable environments.

CONCLUSION

Both ultrasonography and FibroScan CAP showed strong diagnostic capabilities in detecting NAFLD when compared to non-contrast CT. While USG remains accessible and cost-effective, CAP offers slightly better sensitivity and NPV, making it a valuable alternative in clinical settings requiring greater diagnostic precision.

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