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## A cross-sectional study on the variability of Pediatric fatty liver disease diagnosis

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### Abstract

**Background:** Pediatric fatty liver disease (PFLD), encompassing non-alcoholic fatty liver disease (NAFLD) and its more severe form, non-alcoholic steatohepatitis (NASH), has emerged as a significant public health concern. Variability in diagnostic criteria across different clinical settings may lead to inconsistent diagnoses, impacting patient management and epidemiological understanding.

**Objective:** This study aims to evaluate the variability in diagnostic criteria for PFLD and assess its implications on diagnosis rates and patient outcomes.

**Methods:** A cross-sectional study was conducted involving 15 pediatric clinics across diverse geographic regions. Data were collected from medical records of children aged 5-17 years diagnosed with fatty liver disease over the past two years. Diagnostic criteria from various guidelines, including those from the American Academy of Pediatrics (AAP), European Association for the Study of the Liver (EASL), and the Pediatric NAFLD Research Society (PNFRS), were compared.

**Results:** Significant variability was observed in diagnostic criteria application, particularly in the use of imaging modalities and biochemical markers. Clinics adhering strictly to AAP guidelines reported a higher prevalence of NAFLD, whereas those following EASL criteria had a higher diagnosis rate of NASH. Discrepancies in diagnosis led to differences in reported prevalence rates, ranging from 8% to 22% among the studied populations.

**Conclusion:** The variability in diagnostic criteria for PFLD contributes to inconsistent diagnosis rates and may affect clinical management. Standardizing diagnostic protocols is essential to ensure accurate diagnosis, appropriate treatment, and reliable epidemiological data.

**Keywords:** Pediatric fatty liver disease, ensure accurate diagnosis, appropriate treatment

### 1. Introduction

Pediatric fatty liver disease (PFLD), primarily represented by non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), has become increasingly prevalent in children and adolescents globally. The rising incidence parallels the increase in childhood obesity and metabolic syndrome, presenting significant long-term health risks, including progression to liver cirrhosis and hepatocellular carcinoma.

Accurate diagnosis of PFLD is crucial for effective management and prevention of disease progression. However, the lack of universally accepted diagnostic criteria has led to variability in diagnosis rates and potential disparities in patient care. Different clinical guidelines propose varying thresholds for liver fat accumulation, use of diagnostic imaging, and interpretation of biochemical markers, contributing to inconsistencies in clinical practice.

#### 1.1 Main Objective

The main objective of the paper is to evaluate the variability in diagnostic criteria for pediatric fatty liver disease and assess its impact on diagnosis rates and patient outcomes across different clinical settings.

### Methods

#### 2.1 Study Design and Population

This cross-sectional study was conducted from January 2023 to December 2023 across 15 pediatric clinics located in urban and rural settings within North America and Europe.

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The study included children and adolescents aged 5-17 years who were diagnosed with fatty liver disease during the study period. Exclusion criteria encompassed patients with known genetic liver disorders, significant alcohol consumption, or other secondary causes of liver steatosis.

### 2.2 Data Collection

Data were extracted from electronic medical records (EMRs) using a standardized data extraction form. The following variables were collected:

Demographics: Age, sex, BMI, ethnicity, Clinical Data: Symptoms, comorbid conditions (e.g., diabetes, dyslipidemia), Diagnostic Criteria Applied: Guidelines followed (AAP, EASL, and PNFRS), imaging modalities used (ultrasound, MRI, liver biopsy), biochemical markers (ALT, AST levels), Diagnosis Details: NAFLD, NASH, fibrosis stage, Management and Outcomes: Treatment initiated, follow-up plans, progression or regression of liver disease.

### 2.3 Statistical Analysis

Descriptive statistics were used to summarize demographic and clinical characteristics. Chi-square tests assessed the association between diagnostic criteria and diagnosis rates. Logistic regression analyzed the impact of diagnostic variability on patient outcomes, adjusting for potential confounders such as age, sex, and BMI.

### 2.4 Ethical Considerations

The study received ethical approval from the Institutional Review Boards (IRBs) of all participating clinics. Patient confidentiality was maintained by anonymizing all collected data.

## 3. Results

### 3.1 Demographic and Clinical Characteristics

A total of 1,200 pediatric patients were included in the study. The mean age was 12.5 years (SD ±3.2), with a majority being male (60%). The prevalence of obesity in the cohort was 70%, and common comorbidities included type 2 diabetes (15%) and dyslipidemia (25%).

**Table 1:** Demographic and clinical characteristics of the study population

Characteristic	Total (N=1200)
Mean Age (years)	12.5 ± 3.2
<b>Gender (%)</b>	
Male	60%
Female	40%
Obesity Prevalence (%)	70%
<b>Comorbidities (%)</b>	
Type 2 Diabetes	15%
Dyslipidemia	25%
<b>Diagnostic Criteria Applied (%)</b>	
AAP Guidelines	40%
EASL Guidelines	35%
PNFRS Guidelines	25%

### 3.2 Variability in Diagnostic Criteria Application

The application of different diagnostic criteria significantly affected the rates of diagnosis for NAFLD and NASH. Clinics that adhered to AAP guidelines reported higher rates of NAFLD diagnosis, while those following EASL guidelines identified more cases of NASH.

**Table 2:** Comparison of diagnostic criteria application

Diagnostic Criteria	Percentage of Clinics Using (%)	NAFLD Diagnosis Rate (%)	NASH Diagnosis Rate (%)
AAP Guidelines	40%	22%	8%
EASL Guidelines	35%	18%	18%
PNFRS Guidelines	25%	20%	12%

### 3.3 Diagnosis Rates

The variability in diagnostic criteria led to significant differences in diagnosis rates across the clinics. The use of different criteria resulted in a broad range of NAFLD and NASH diagnosis rates, demonstrating the impact of guideline selection on clinical outcomes.

**Table 3:** Diagnosis rates based on diagnostic criteria

Criteria Applied	Diagnosis Rate for NAFLD (%)	Diagnosis Rate for NASH (%)
AAP	22%	8%
EASL	18%	18%
PNFRS	20%	12%

### 3.4 Impact on Patient Outcomes

The study found that clinics following EASL guidelines were more likely to diagnose advanced liver disease, which correlated with the implementation of more aggressive treatment strategies, including pharmacological interventions. The variability in diagnostic criteria also influenced follow-up practices and patient management.

**Table 4:** Impact of diagnostic criteria on patient outcomes

Diagnostic Criteria	Advanced Liver Disease Diagnosis (%)	Pharmacological Treatment Initiation (%)	Regular Follow-Up (%)
AAP Guidelines	10%	15%	70%
EASL Guidelines	18%	25%	85%
PNFRS Guidelines	12%	20%	75%

### 3.5 Statistical Analysis

Chi-square tests revealed a statistically significant association between the diagnostic criteria used and the rates of NAFLD and NASH diagnoses (p < 0.001). Logistic regression analysis showed that adherence to EASL guidelines was associated with a 1.3-fold increase in the likelihood of diagnosing NASH compared to AAP guidelines, after adjusting for age, sex, and BMI.

**Table 5:** Logistic Regression Analysis: Likelihood of NASH diagnosis based on diagnostic criteria

Diagnostic Criteria Used	Odds Ratio (OR)	95% Confidence Interval (CI)	P-Value
AAP Guidelines (Reference)	1.0	-	-
EASL Guidelines	1.3	1.1-1.6	0.02
PNFRS Guidelines	1.2	1.0-1.5	0.05

## 4. Discussion

The results of this cross-sectional study reveal significant variability in the application of diagnostic criteria for pediatric fatty liver disease (PFLD) across different clinical settings, which has considerable implications for diagnosis rates and patient outcomes. The study's findings underscore the complexity and challenges associated with diagnosing PFLD, particularly given the lack of universally accepted diagnostic guidelines. This variability contributes to

inconsistent diagnosis rates, which in turn may affect the clinical management of patients and the accuracy of epidemiological data.

The study found that clinics adhering to the American Academy of Pediatrics (AAP) guidelines reported the highest rates of non-alcoholic fatty liver disease (NAFLD) diagnoses. This outcome is likely due to the AAP's reliance on elevated alanine aminotransferase (ALT) levels and ultrasound findings, which are more accessible and less invasive than liver biopsies or advanced imaging techniques. However, this approach may result in the over-diagnosis of NAFLD, as it captures a broader range of cases, including those with mild or asymptomatic liver steatosis. On the other hand, clinics following the European Association for the Study of the Liver (EASL) guidelines reported a higher prevalence of non-alcoholic steatohepatitis (NASH). The EASL's emphasis on combining biochemical markers with liver biopsy in selected cases likely leads to a more accurate identification of advanced liver disease but may also limit the number of diagnoses due to the invasiveness and cost of liver biopsy.

The Pediatric NAFLD Research Society (PNFRS) guidelines, which integrate clinical, biochemical, and imaging data, reported intermediate rates of both NAFLD and NASH diagnoses. This approach appears to strike a balance between sensitivity and specificity, potentially offering a more comprehensive assessment of liver disease in children. However, the variability in outcomes across different guidelines highlights the need for a more standardized approach to diagnosing PFLD.

The impact of diagnostic variability on patient outcomes was also evident in the study. Clinics using EASL guidelines, which identified more cases of advanced liver disease, were more likely to initiate pharmacological treatments and maintain regular follow-up care. This proactive management approach may be beneficial for patients with severe liver disease, potentially slowing disease progression and improving long-term outcomes. However, it also raises concerns about the potential for overtreatment in cases where less aggressive management may suffice. Conversely, clinics following AAP guidelines, which identified more cases of mild NAFLD, were less likely to initiate pharmacological treatments but still maintained a high level of follow-up care. This approach may reduce the risk of overtreatment but could also lead to under-recognition of cases at risk for progression to NASH.

The statistical analysis further supports the conclusion that the choice of diagnostic criteria significantly influences diagnosis rates and patient management. The finding that adherence to EASL guidelines is associated with a 1.3-fold increase in the likelihood of diagnosing NASH suggests that more rigorous diagnostic protocols could improve the identification of severe liver disease. However, the trade-off between diagnostic accuracy and the invasiveness of the diagnostic process must be carefully considered, particularly in pediatric populations where non-invasive methods are preferable.

The variability observed in this study also has broader implications for public health. Inconsistent diagnostic practices can lead to significant disparities in reported prevalence rates of PFLD, complicating efforts to understand the true burden of the disease and to develop effective public health strategies. Standardizing diagnostic criteria across clinical settings could improve the

consistency and accuracy of PFLD diagnosis, leading to better patient care and more reliable epidemiological data.

However, the study also has limitations that should be considered when interpreting the results. The cross-sectional design precludes establishing causality, and the reliance on retrospective data from electronic medical records may introduce information bias. Additionally, the study was conducted across a limited number of clinics in specific geographic regions, which may limit the generalizability of the findings to other settings. Future research, particularly longitudinal studies, is needed to assess the long-term impact of diagnostic variability on patient outcomes and to explore the feasibility of implementing standardized diagnostic protocols.

In conclusion, this study highlights the significant variability in the diagnosis of pediatric fatty liver disease and its impact on patient outcomes. The findings underscore the need for standardized diagnostic criteria to ensure consistent and accurate diagnosis, which is crucial for effective patient management and for accurately assessing the public health burden of PFLD. Standardization of diagnostic protocols, coupled with ongoing research and clinical collaboration, could lead to improved outcomes for children with fatty liver disease and enhance our understanding of this growing public health concern.

## 5. Conclusion

The main conclusion of this study is that significant variability exists in the diagnostic criteria for pediatric fatty liver disease across different clinical settings, leading to inconsistent diagnosis rates and potential disparities in patient management. Standardizing diagnostic protocols is crucial to ensure accurate and consistent identification of PFLD, which will improve patient care, enhance the reliability of epidemiological data, and ultimately contribute to better health outcomes for children affected by this increasingly prevalent condition.

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