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EFFECTIVENESS OF NON-INVASIVE METHODS FOR ASSESSING FIBROSIS IN PATIENTS WITH NAFLD AND IR

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Abstract. Introduction: Non-alcoholic fatty liver disease (NAFLD) is a widespread condition that can progress to severe liver complications, including fibrosis and cirrhosis. Early detection of liver fibrosis is critical for preventing disease progression and reducing the risk of liver-related complications. This study aimed to assess the utility of non-invasive methods, including elastography and fibrosis scoring systems, in evaluating liver fibrosis in patients with NAFLD and insulin resistance (IR).

Methods: This study enrolled 76 patients, consisting of 45 females and 31 males, aged 25 to 60 years. All participants underwent biochemical tests, transient elastography for liver stiffness measurement, and non-invasive fibrosis scoring using FibroTest, FIB-4, and NAFLD Fibrosis Score (NFS). Descriptive statistics were used to summarize the data, and correlation analysis was performed to evaluate the relationships between elastography and the fibrosis scores.

Results: The results indicated that liver stiffness measured by elastography was significantly correlated with the fibrosis scores (FibroTest, FIB-4, NFS), with strong positive correlations between these methods ($r = 0.929$, $p < 0.01$; $r = 0.883$, $p < 0.01$; $r = 0.533$, $p < 0.01$). Biochemical markers showed mild deviations, but they were not sufficient to conclusively indicate advanced fibrosis on their own. However, the combination of elastography and non-invasive fibrosis scores effectively identified patients with early stages of fibrosis.

Conclusion: The integration of elastography with non-invasive fibrosis scoring systems (FibroTest, FIB-4, and NFS) offers a reliable and non-invasive approach to accurately assess liver fibrosis in NAFLD patients with comorbid insulin resistance. This combination of methods provides a promising alternative to liver biopsy for diagnosing and monitoring fibrosis, enabling more effective patient management and early intervention.

Key words: *insulin resistance, nonalcoholic fatty liver disease, insulin, liver, metabolic syndrome.*

Introduction. Non-alcoholic fatty liver disease (NAFLD) is a chronic condition characterized by fat accumulation in the liver, not due to alcohol consumption [4], [19]. Affecting 25–30% of adults globally, NAFLD's prevalence is rising, largely due to obesity, type 2 diabetes, and metabolic syndrome [23], [16]. If untreated, it can progress to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, liver failure, and hepatocellular carcinoma, significantly impacting quality of life and increasing cardiovascular disease risk [2].

A common comorbidity in NAFLD patients is insulin resistance (IR), where the body's cells become less responsive to insulin, leading to higher blood glucose [3], [15]. IR accelerates liver damage, worsening NAFLD progression and increasing the risk of cardiovascular disease, type 2 diabetes, and liver-related complications.

Early diagnosis of liver fibrosis is essential, as the fibrosis stage is a key predictor of outcomes [14]. Advanced fibrosis is linked to severe liver complications and mortality, but early stages are often asymptomatic, making detection challenging. Identifying significant fibrosis (stages F2-F4) allows for early interventions to slow disease progression and reduce morbidity [13].

Liver biopsy remains the gold standard for diagnosing fibrosis, but it is invasive, carries risks, and is not practical for widespread screening [7]. Non-invasive methods like elastography (e.g., FibroScan) estimate liver stiffness and correlate with fibrosis stages [21]. They are quick, painless, and suitable for outpatient settings [24].

Clinical scoring systems, such as FIB-4, FibroTest, and NAFLD Fibrosis Score (NFS), use routine lab data to assess fibrosis risk [22], [6]. Though less precise than biopsy, they effectively screen and stratify patients by risk [26].

Non-invasive methods are promising for early NAFLD diagnosis and management. As these methods become more accessible, they reduce the need for biopsy, facilitating safer and more efficient screening. Including IR assessments can help identify high-risk patients, improving overall management of NAFLD.

The aim of the study is to assess the effectiveness of non-invasive methods for diagnosing liver fibrosis in patients with non-alcoholic fatty liver disease (NAFLD) and insuline resistance (IR).

Materials and Methods. This study involved 76 patients (45 females, 31 males), aged 25 to 60 years, diagnosed with non-alcoholic fatty liver disease (NAFLD) and insulin resistance (IR). Participants were selected based on strict criteria, with diagnostic evaluations to confirm NAFLD and exclude other liver or systemic diseases. All patients met diagnostic criteria for NAFLD and IR, including elevated fasting insulin and a HOMA-IR index. Exclusion criteria included viral hepatitis (HBV, HCV, HDV), liver cirrhosis, excessive alcohol consumption, toxic or drug-induced liver diseases, autoimmune liver disorders, medications linked to liver injury, and any chronic decompensated conditions, including diabetes mellitus.

All patients underwent a complete blood count (CBC) and biochemical analysis, assessing liver enzymes (ALT, AST), bilirubin, and glucose levels, to evaluate liver function and metabolic health. Abdominal ultrasound was performed to assess the hepatobiliary system and rule out other liver conditions, while liver stiffness was measured using transient elastography to quantify fibrosis. Fibrosis was also assessed using the FibroTest, FIB-4, and NAFLD Fibrosis Score (NFS), which integrate clinical and laboratory parameters to estimate fibrosis risk.

Descriptive statistics (means and standard deviations) were calculated for primary variables, and the Mann-Whitney U test was applied to compare fibrosis scores across methods, with significance set at $p < 0.01$. Pearson's correlation coefficient was calculated to examine the relationships between elastography and fibrosis scores, confirming associations. Statistical analyses were performed using [Specify Software, e.g., SPSS version XX].

Results. To fulfill the study objectives, all patients underwent an extensive series of clinical, laboratory, and instrumental assessments. Initially, detailed medical histories were taken, including the collection of patient-reported complaints. The next stage comprised laboratory and instrumental evaluations aimed at identifying key indicators of liver pathology. Biochemical results shown in table 1.

Table 1

Biochemical indicators of enzyme metabolism in patients with NAFLD and IR

Biochemical indicators	Patients with NAFLD and IR
ALT, U/L	61.16 ± 6.98*
AST, U/L	56.18 ± 4.76*
De Ritis Index	0.93 ± 0.04*
total bilirubin, μmol/L	14.15 ± 1.94*
Total protein, g/L	68.7 ± 2.84*
Albumine, g/L	39.37 ± 1.97*
GGT, U/L	46.71 ± 12.59*
ALP, U/L	113.3 ± 20.65*
Glucose, mmol/L	6.14 ± 0.44*
HOMA-IR	20.24 ± 3.69*

Note: The significance of the difference was calculated according to the Mann-Whitney test – $p < 0.05$.

The laboratory results for the patient cohort reveal notable deviations in several key markers of liver function and metabolism, indicative of liver involvement in NAFLD patients. Both ALT (normal range: 10–40 U/L) and AST (normal range: 10–40 U/L) levels were increased by approximately 20–25% above upper normal reference values, suggesting mild hepatic injury. The De Ritis ratio (AST/ALT) remained below 1, indicating a pattern of liver enzyme imbalance often associated with liver inflammation seen in NAFLD. Total protein levels (normal range: 60–80 g/L) were slightly

lower than normal, with a decrease of around 5% below the reference range, which could suggest subtle liver dysfunction. However, albumin levels (normal range: 35–50 g/L) were close to the lower end of normal, indicating relatively preserved synthetic liver function. Gamma-glutamyl transferase (GGT) (normal range: 10–60 U/L) and alkaline phosphatase (ALP) (normal range: 35–104 U/L) levels were mildly elevated, by about 10–15% above their respective upper normal limits. These markers are often associated with liver and biliary tract involvement, highlighting the possible effect of NAFLD on biliary function. Glucose levels (normal range: 3.9–5.5 mmol/L) were roughly 10% above the upper normal reference limit, consistent with impaired glucose tolerance commonly seen in patients with insulin resistance. The HOMA-IR index (normal range: 0.5–2.5) showed substantial elevation, exceeding normal values by more than 50%, underscoring significant metabolic disturbance in this group. These biochemical deviations, though suggestive of liver involvement and metabolic dysfunction, do not independently confirm advanced fibrosis, emphasizing the necessity of utilizing complementary non-invasive methods, such as elastography and fibrosis scoring indices, for a comprehensive and accurate assessment of liver fibrosis in NAFLD patients with insulin resistance.

The elastographic density of the liver in patients with NAFLD is measured at an average value of 7,21 ± 1,24 kPa. This result reflects the stiffness of the liver, which is commonly used to assess the degree of fibrosis.

Table 2

Results of non-invasive fibrosis methods

	FibroTest	FIB-4	NFS
NAFLD	0,42 ± 0,09*	1,56 ± 0,19*	–1,2 ± 0,86*

Note: Significance of the difference according to the Kruskel – Wallis test: * – $p < 0.01$.

The results for the non-invasive fibrosis scoring systems in patients with NAFLD are as follows (Table 2):

FibroTest: The average score falls within the range indicative of moderate liver fibrosis. This score suggests the presence of some degree of liver fibrosis, although it has not reached advanced stages.

FIB-4: The average score falls within the range that typically suggests significant liver fibrosis. This score indicates the potential for moderate to advanced fibrosis, which can help estimate the likelihood of progression to more severe stages of liver damage.

NFS (NAFLD Fibrosis Score): The average score is negative but still within a range that indicates some degree of liver fibrosis. While the fibrosis is not advanced in this group, the score suggests that there is a risk of progression to higher stages of fibrosis over time.

In addition, we calculated the presence of a correlation between elastography and the fibrosis scoring systems (FibroTest, FIB-4, NFS). The observed correlation coefficients ($r = 0.94$ for FibroTest, $r = 0.88$ for FIB-4, and $r = 0.53$ for NFS) demonstrate a high consistency between elastography and these tests, further supporting the use of these non-invasive techniques in assessing liver fibrosis and providing additional confirmation of the presence and extent of liver damage.

Discussion. This study emphasizes the importance of combining non-invasive diagnostic methods, such as elastography and biochemical scoring systems, for assessing liver fibrosis in patients with NAFLD and insulin resistance (IR). Given the increasing prevalence of these conditions, early and accurate diagnosis of liver fibrosis is crucial for effective management. While biochemical markers like ALT and AST showed slight elevation, these alone did not strongly indicate significant fibrosis [11], [27]. Other markers, including bilirubin, total protein, and albumin, also exhibited mild changes, which did not suggest advanced fibrosis or cirrhosis [5].

Elastography, however, provided a different perspective, indicating the presence of mild to moderate fibrosis. This is consistent with findings that elastography is sensitive and reliable for detecting liver

stiffness, which correlates directly with the extent of fibrosis [26]. The contrast between the mild biochemical alterations and the moderate fibrosis observed on elastography highlights the need for integrating elastography with biochemical tests, as the latter are often insufficient for accurately staging fibrosis, especially in its early stages.

The fibrosis scoring systems further supported the elastography results. The FibroTest score suggested some degree of fibrosis, which aligned with the elastographic findings [1]. Similarly, the FIB-4 score indicated possible advanced fibrosis, reinforcing the elastography results [20]. The NFS score, while negative, still indicated a low probability of advanced fibrosis, suggesting that its less extreme value did not rule out the presence of fibrosis, as seen in more severe disease states [17].

The strong correlations between elastography and the fibrosis scores underscore the value of combining these non-invasive methods for assessing liver fibrosis. The high correlation with both FibroTest and FIB-4 confirms the consistency of elastography in detecting fibrosis, making it a valuable tool in the overall assessment of liver damage. This combined approach allows for a more accurate understanding of liver pathology, helping to identify patients at risk of disease progression [9], [8].

Overall, relying on multiple diagnostic methods in clinical practice offers clear advantages. While scoring systems and biochemical tests are useful, they can miss early-stage fibrosis. Elastography, which detects changes in liver stiffness directly related to fibrosis, complements these methods, creating a comprehensive approach for early detection and better patient stratification. This combined strategy can lead to earlier interventions, improving outcomes and helping manage comorbidities such as cardiovascular disease and diabetes, ultimately reducing disease progression and enhancing patient care [18], [12], [10], [28].

Conclusions. The combination of elastography and non-invasive fibrosis scoring systems (FibroTest, FIB-4, NFS) provides a reliable and comprehensive approach to diagnosing and staging liver fibrosis in patients with NAFLD and insulin resistance.

These methods enable early detection of liver fibrosis, allowing for timely interventions that can prevent disease progression and reduce liver-related complications.

The integration of these tools into clinical practice will improve the diagnosis and management of liver fibrosis in NAFLD patients, ultimately leading to better long-term health outcomes.

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ЕФЕКТИВНІСТЬ НЕІНВАЗИВНИХ МЕТОДІВ ОЦІНКИ ФІБРОЗУ D ПАЦІЄНТІВ З НАЖХП ТА ІР

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Анотація. Вступ. Неалкогольна жирова хвороба печінки (НАЖХП) є поширеним захворюванням, яке може прогресувати до важких уражень печінки, включно з фіброзом і цирозом. Раннє виявлення фіброзу печінки є критичним для запобігання прогресуванню хвороби та зниження ризику ускладнень. Мета цього дослідження – оцінити ефективність неінвазивних методів, зокрема еластографії та систем оцінки фіброзу, для визначення фіброзу печінки в пацієнтів з НАЖХП та інсуліновою резистентністю (ІР).

Методи. До дослідження були залучені 76 пацієнтів (45 жінок і 31 чоловік) віком від 25 до 60 років. Усі учасники пройшли біохімічні тести, трансієнтну еластографію для вимірювання жорсткості печінки та неінвазивну оцінку фіброзу за допомогою FibroTest, FIB-4 та NAFLD Fibrosis Score (NFS). Для аналізу даних були використані описова статистика й кореляційний аналіз.

Результати. Результати показали, що жорсткість печінки, виміряна еластографією, мала значущу кореляцію з результатами систем оцінки фіброзу (FibroTest, FIB-4, NFS), з високими позитивними кореляціями між цими методами ($r = 0,929$, $p < 0,01$; $r = 0,883$, $p < 0,01$; $r = 0,533$, $p < 0,01$). Біохімічні маркери показали незначні відхилення, але вони не були достатніми для однозначного визначення розвитку фіброзу. Однак поєднання еластографії та неінвазивних систем оцінки фіброзу ефективно ідентифікувало пацієнтів із початковими стадіями фіброзу.

Висновки. Інтеграція еластографії з неінвазивними системами оцінки фіброзу (FibroTest, FIB-4 та NFS) є надійним і неінвазивним підходом для точної оцінки фіброзу печінки у пацієнтів з НАЖХП та ІР. Цей підхід є перспективною альтернативою біопсії печінки для діагностики й моніторингу фіброзу, що дає змогу забезпечити ефективніше управління пацієнтами та раннє втручання.

Ключові слова: *інсулінорезистентність, неалкогольна жирова хвороба печінки, інсулін, печінка, метаболічний синдром.*

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