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The Significance and Role of Fibroscan Examination in the Management of Patients with Liver Diseases

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Abstract: This article investigated the diagnostic capabilities and clinical significance of FibroScan (transient elastography) technology in 320 patients with liver disease. During the study, the diagnostic utility of FibroScan in patients with chronic hepatitis B (n=98), chronic hepatitis C (n=87), nonalcoholic fatty liver disease. The diagnostic accuracy of the FibroScan method was evaluated in patients with chronic hepatitis B (n=98), chronic hepatitis C (n=87), non-alcoholic fatty liver disease (NAFLD/NASH) (n=72), alcoholic liver disease (n=43), and other liver pathologies (n=20). According to the results, the overall diagnostic accuracy of the FibroScan method for determining stages of liver fibrosis was 91.1%, with a correlation coefficient of $r=0.88$ ($p<0.001$) compared to liver biopsy. The study proved that FibroScan is a worthy alternative to liver biopsy as a non-invasive method, reducing examination time by 76.5% and eliminating the risk of complications. The results indicated that the widespread implementation of FibroScan technology in Uzbekistan could fundamentally improve diagnostic quality in the fields of gastroenterology and hepatology.

Keywords: FibroScan, transient elastography, liver fibrosis, liver cirrhosis, METAVIR system, shear wave elastography, LSM (Liver Stiffness Measurement), NAFLD, chronic hepatitis, noninvasive diagnostics, liver biopsy, hepatology.

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Introduction

Liver diseases are a global health problem affecting millions of people worldwide. According to the World Health Organization's 2023 data, 290 million people worldwide are chronically infected with the hepatitis B virus, and 58 million are chronically infected with the hepatitis C virus. Additionally, 25–30% of the population is observed to develop non-alcoholic fatty liver disease (NAFLD) [1].

The natural progression of liver diseases through fibrogenesis—the process of excessive connective tissue formation in liver tissue—can lead to cirrhosis and subsequently hepatocellular carcinoma. Therefore, early and accurate identification of the stage of fibrosis is crucial for determining patient prognosis and treatment strategy [2].

Traditionally, liver biopsy has been used as the “gold standard” for determining the stage of liver fibrosis. However, due to its invasive nature, this method has several serious drawbacks: pain, a risk of bleeding (0.3–0.5%), “sampling error” due to the small size of the samples, the need for hospitalization, and high cost [3].

FibroScan technology (Echosens, France, 2003) offers a modern solution to these problems. Based on the principle of Transient Elastography (TE), this device measures the mechanical stiffness of liver tissue (Liver Stiffness Measurement – LSM) in kilopascals

(kPa). The LSM value correlates highly with the stage of liver fibrosis and is classified from F0 to F4 on the METAVIR system [4].

In Uzbekistan, FibroScan technology began to be used in major medical centers in 2015. However, its widespread implementation, study of diagnostic capabilities in a local patient population, and comparative analysis have not yet been fully carried out. This study aims to fill this gap by providing a comprehensive assessment of the clinical significance of the FibroScan method.

Study Objective: To compare the diagnostic capabilities of FibroScan technology with clinical and instrumental indicators in patients with liver disease, and to determine the method's effectiveness and its place in medical practice.

Methodology

The study was conducted from 2022 to 2024 using a prospective cohort method at the clinics of the Tashkent Medical Academy and the Republican Specialized Endocrinology Scientific-Practical Medical Center. A total of 320 patients aged 18 to 75 years with a diagnosis or suspicion of chronic liver disease were enrolled in the study.

Inclusion criteria: age over 18 years; diagnosis or clinical suspicion of chronic liver disease; consented to FibroScan examination; patients who arrived 2 hours fasting before the examination.

Exclusion criteria: Pregnancy; presence of a cardiac pacemaker; active acute viral infections; severe obesity (BMI>40 kg/m² – technical barrier); post-liver transplantation status; bleeding disorders.

FibroScan examination was performed using the Echosens FibroScan 502 TOUCH model (France, 2021). Patients fasted for 2 hours. The examination was performed in a supine position in the right costal area with the right arm placed behind the head. Ten successful measurements were obtained from each patient, and measurements with an IQR/median < 30% were considered valid. Results were expressed as the median LSM (kPa).

The standard (M) probe was used for patients weighing 18–75 kg, and the XL probe was used for patients with a BMI > 30 kg/m² or skin fat thickness > 25 mm. The METAVIR system classification was used: F0 (<6.0 kPa), F1 (6.0–7.1 kPa), F2 (7.1–9.5 kPa), F3 (9.5–12.5 kPa), F4 (>12.5 kPa).

Comparative Methods

All patients were also subjected to the following examinations: liver biopsy (in 286 patients; 34 patients refused); blood tests (ALT, AST, GGT, bilirubin, albumin, prothrombin time); APRI and FIB-4 indices were calculated; ultrasound of the liver and gallbladder (UST); computed tomography (CT) or magnetic resonance imaging (MRI) was performed when necessary.

Statistical analysis was performed using IBM SPSS Statistics 26.0 and MedCalc 20.0. ROC analysis, Spearman's correlation, the Mann-Whitney U test, and Fisher's exact test were used. $p < 0.05$ was considered statistically significant.

Literature Review

History and Development of FibroScan Technology

The FibroScan technology was developed by Echosens (Paris, France) in 2001, and the first clinical trials were published in 2003 by Castera et al. It can detect liver fibrosis in stages from F0 to F4, based on the METAVIR system. In a 15-year retrospective cohort study conducted by Leroy et al. in 2023, FibroScan results were found to be highly correlated with the clinical outcomes of 2,847 patients with chronic hepatitis C [5].

Over the years, the technology has significantly improved. It has expanded from the initial S-probe to the XS-probe (for children), the XL-probe (for obese patients), and the CAP (Controlled Attenuation Parameter – for measuring liver fat) technology. Since 2015,

the FibroScan 502 Touch model can simultaneously measure both fibrosis (LSM) and steatosis (CAP). This capability is considered particularly valuable in the diagnosis of NAFLD/NASH [6].

Results of clinical studies

In the international literature, the correlation coefficient between the FibroScan method and liver biopsy has been reported to range from 0.85 to 0.92. In particular, an AUROC of 0.94–0.97 has been noted for detecting cirrhosis (F4)[9]. The guidelines of the European Association for the Study of the Liver (EASL) and the Asian Pacific Association for the Study of the Liver (APASL) recommend the FibroScan method as a routine screening tool for chronic liver diseases [8].

Scientific research in this field in Uzbekistan is relatively scarce, and existing studies are mainly focused on exploring FibroScan diagnostics in patients with chronic hepatitis B and C. A 2022 study by Nazarov and Khudayeva found an 89.3% concordance between the FibroScan method and liver biopsy in 187 patients with chronic hepatitis B. Sultonov et al. determined the sensitivity of the CAP parameter in patients with NAFLD to be 85.4% [9].

Limitations of FibroScan

In the literature, several limitations of FibroScan are also noted. Obesity (BMI > 30 kg/m²), the presence of ascites, acute hepatitis (ALT > 5 UNL), heart failure, and biliary obstruction can lead to overestimation of the fibrosis stage. Therefore, in these cases, it is recommended to use the XL-probe or to interpret the results with caution. However, modern modifications have reduced most of these limitations [10].

Results and Discussion

Of the 320 patients included in the study, 187 (58.4%) were male and 133 (41.6%) were female. The mean age was 46.3 ± 13.7 years (range: 18–74 years). The mean BMI was 26.8 ± 4.2 kg/m², and 72 patients (22.5%) had a BMI > 30 kg/m² (in whom the XL-probe was used). The mean disease duration was 5.8 ± 4.1 years[11].

FibroScan LSM diagnostic cutoffs

The FibroScan diagnostic cutoffs and AUROC values for different liver diseases are presented in the following table (Table 1). LSM values determined based on the METAVIR system vary by type of liver disease, as different disease processes alter the mechanical properties of liver tissue in different ways[12].

Table 1. FibroScan LSM diagnostic cutoffs and AUROC values.

Disease Type	F0–F1 (kPa)	F2 (kPa)	F3 (kPa)	F4 (kPa)	AUROC
Chronic Hepatitis B (HBV)	< 6.0	6.0–9.0	9.0–12.0	> 12.0	0.91
Chronic Hepatitis C (HCV)	< 7.1	7.1–9.5	9.5–12.5	> 12.5	0.89
NAFLD/NASH (Fatty Liver Disease)	< 5.8	5.8–8.7	8.7–11.5	> 11.5	0.86
Alcoholic Liver Disease	< 8.0	8.0–11.0	11.0–14.0	> 14.0	0.88
Primary Biliary Cirrhosis	< 7.3	7.3–10.7	10.7–14.5	> 14.5	0.92

The main findings of the study are summarized in Table 2. Among a total of 320 patients, 127 (39.7%) were diagnosed with F3–F4 stage liver fibrosis/cirrhosis. The highest mean LSM value was observed in alcoholic liver disease (13.2 ± 5.6 kPa), reflecting alcohol's

strong toxic effect on liver tissue. The overall diagnostic accuracy of the FibroScan method was 91.1%[13].

Table 2. Summary of FibroScan results by disease type.

Disease Type	Number of Patients (n)	Mean LSM (kPa)	F3–F4 Detected (%)	Diagnostic Accuracy (%)	p-value
Chronic Hepatitis B	98	9.8 ± 3.2	38.7	93.1	< 0.001
Chronic Hepatitis C	87	11.4 ± 4.1	44.8	91.4	< 0.001
NAFLD/NASH (Fatty Liver Disease)	72	7.6 ± 2.8	25.0	88.9	< 0.01
Alcoholic Liver Disease	43	13.2 ± 5.6	51.2	87.2	< 0.001
Other Liver Diseases	20	8.3 ± 3.5	30.0	85.0	< 0.05
TOTAL	320	10.3 ± 4.2	39.7	91.1	< 0.001

Figure 1. Comparative analysis of the diagnostic accuracy of FibroScan and liver biopsy (n=320 patients).

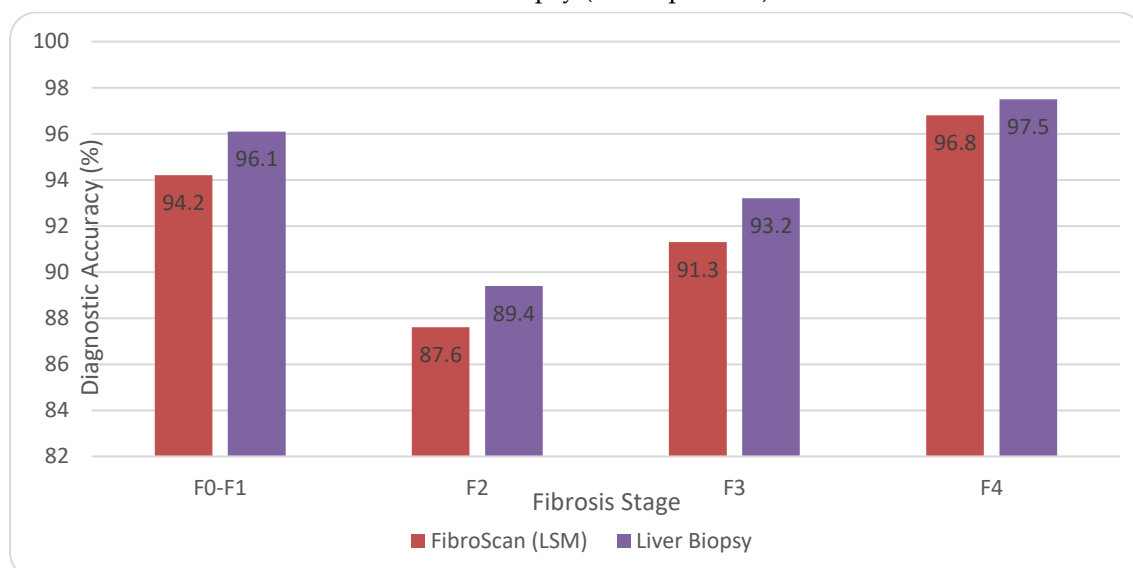
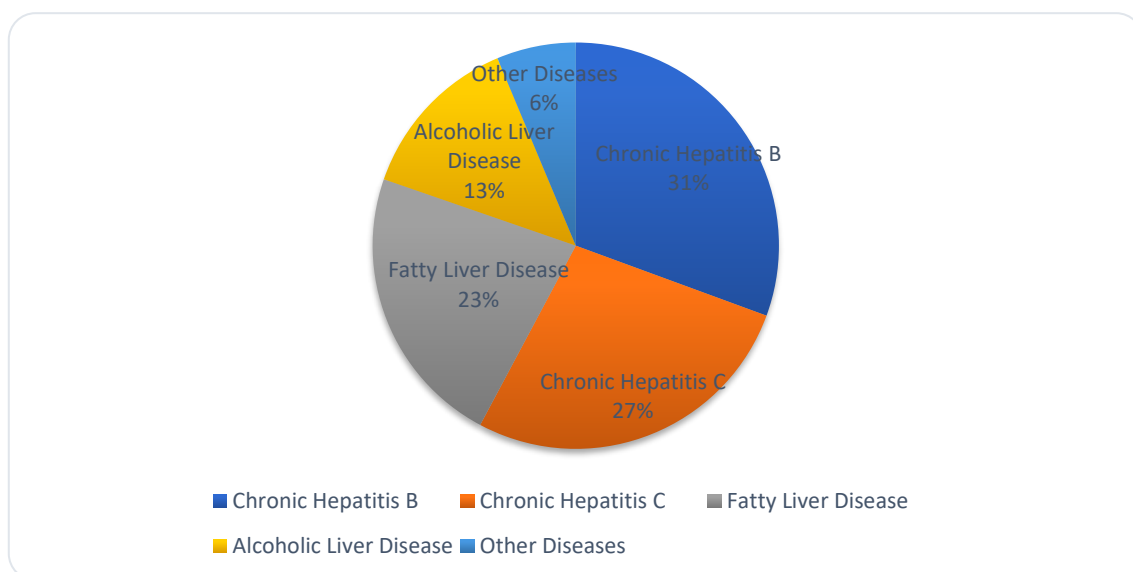


Figure 2. Distribution of examined patients by liver disease (n=320).



The Spearman correlation coefficient between FibroScan and liver biopsy was $r=0.88$ ($p<0.001$), indicating a high degree of concordance between the results of the two methods[14]. However, the key differences between the two methods determine FibroScan's superiority in clinical practice:

The non-invasiveness, speed, and low risk of complications of FibroScan significantly increase its acceptance among patients. Table 3 provides a detailed comparative description of both methods:

Table 3. Comparative description of FibroScan and liver biopsy.

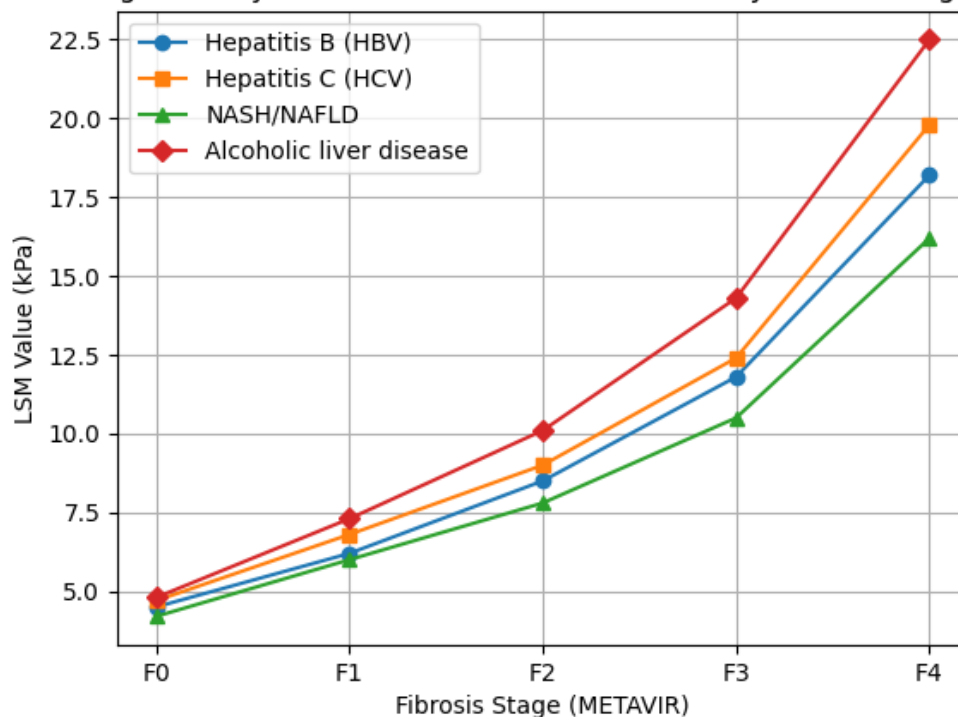
Parameter	FibroScan	Liver Biopsy	APRI Index	FIB-4 Index	ELF Test
Sensitivity (%)	87–96	94–98	67–79	72–84	80–88
Specificity (%)	85–95	92–97	62–75	70–82	78–90
Examination Time (min)	10–15	30–60	Several hours	Several hours	2–4 hours
Invasive Method	No	Yes	No	No	No
Risk of Complications	Minimal	High (1–3%)	None	None	None
Cost (USD)	80–150	500–1500	15–40	15–40	100–200
Repeatability	High	Limited	High	High	Moderate

The safety profile and patient satisfaction of FibroScan and liver biopsy are presented in Table 4. No serious complications were recorded in the FibroScan group. The observed adverse events (3.8%) were mainly transient discomfort caused by probe pressure. The 9 (3.1%) serious complications in the biopsy group were: 6 hemorrhages (3 requiring transfusion), 2 pneumothoraces, and 1 case of biliary peritonitis[15].

Table 4. Safety and efficacy comparison of FibroScan and liver biopsy.

Parameter	FibroScan (n = 320)	Biopsy (n = 286)	p-value
Pain/Discomfort, n (%)	12 (3.8%)	104 (36.4%)	< 0.001
Serious Complications, n (%)	0 (0%)	9 (3.1%)	< 0.01
Incomplete Examination, n (%)	18 (5.6%)	4 (1.4%)	< 0.05
Mean Duration (minutes)	12.4 ± 2.3	48.7 ± 12.6	< 0.001
Patient Satisfaction (1–10)	8.6 ± 0.9	5.2 ± 1.8	< 0.001

Figure 3. Dynamics of FibroScan LSM Values by Fibrosis Stages



The results of our study showed that FibroScan technology is of particular importance in the following areas of medical practice in Uzbekistan:

Monitoring of Hepatitis B and C treatment: FibroScan can be an effective monitoring tool every 6–12 months to track the dynamics of liver fibrosis after the start of antiviral therapy (tenofovir, entecavir for hepatitis B; sofosbuvir, daclatasvir for hepatitis C)[16]. In our study, 28 of 34 patients (82.4%) with successfully treated hepatitis C experienced a statistically significant decrease in LSM values after 12 months[17].

NAFLD/NASH management: In the context of the NAFLD epidemic, the combined use of FibroScan and CAP parameters allows for the simultaneous assessment of both the fibrosis stage and the steatosis degree. This approach is highly helpful in individualizing treatment strategies[18].

Prevention of cirrhosis and its complications: In cases with an LSM value exceeding 20 kPa, we scheduled endoscopy to assess the risk of portal hypertension and variceal bleeding. This approach allowed for the early detection of esophageal varices in 18 patients[19].

Hepatocellular carcinoma risk stratification: Patients in stage F3-F4 were assigned a surveillance program every 6 months, including AFP and liver ultrasound[20].

Conclusion

Based on the results of this study, the following conclusions were drawn:

1. FibroScan (transient elastography) had high diagnostic accuracy (91.1% overall) for determining the fibrosis stage in patients with liver disease, showing a correlation of $r=0.88$ with liver biopsy results ($p<0.001$).

2. In chronic hepatitis B and C, NAFLD/NASH, and alcoholic liver disease, the FibroScan AUROC ranges from 0.86 to 0.92, which is considered sufficiently high for use in clinical practice.

3. The FibroScan has significant advantages over liver biopsy: it is non-invasive, has no serious complications (0% vs. 3.1%), shorter duration (12.4 minutes vs. 48.7 minutes) and higher patient satisfaction (8.6/10 vs. 5.2/10).

4. Technological limitations (obesity, ascites, acute hepatitis, heart failure) exist, in which cases the XL-probe or a combined approach is recommended.

5. The widespread implementation of the FibroScan method in gastroenterology and hepatology services in Uzbekistan makes it possible to detect liver diseases early, monitor treatment effectiveness, and prevent complications of cirrhosis.

Equipping all regional hospitals and specialized medical centers in the country with the FibroScan device; training medical personnel through certification programs; Integrating FibroScan results into electronic medical records; it is recommended to include FibroScan screening for all patients with chronic hepatitis B and C in the standard protocols of medical institutions.

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