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Diagnostic accuracy of shear wave elastography for staging liver fibrosis in diabetic patients with NAFLD

Non-alcoholic fatty liver disease (NAFLD) has become one of the leading chronic hepatic disorders worldwide, largely as a consequence of reduced physical activity and widespread intake of calorie-dense diets. The burden of NAFLD is particularly pronounced in South Asian countries, where its prevalence in India alone has been reported to vary between 9% and 32% [1, 2].

Despite its common occurrence, the condition is frequently underdiagnosed because many patients do not exhibit clinical symptoms.

Pathogenetically, NAFLD encompasses a continuum of liver alterations characterized by excessive accumulation of triglycerides within hepatocytes. This steatotic process can trigger hepatocellular damage, inflammatory cascades, and progressive fibrogenesis, occurring independently of secondary causes such as alcohol misuse or viral infections [3, 4].

Disease expression is highly heterogeneous: although a notable proportion of affected individuals present with simple steatosis (non-alcoholic fatty liver, NAFL), another subset transitions to non-alcoholic steatohepatitis (NASH), which carries a substantial risk for advanced fibrosis and cirrhosis if untreated. Moreover, NAFLD is recognized as a significant contributor to cardiovascular morbidity and liver-related outcomes, including cirrhosis and hepatocellular carcinoma. Lifestyle-oriented preventive strategies — namely structured weight loss, regular physical activity, and dietary adjustments — remain the cornerstone of early intervention [1, 2, 5].

A strong, bidirectional association has been documented between NAFLD and type 2 diabetes mellitus (T2DM). T2DM promotes more rapid progression of NAFLD, while individuals with NAFLD demonstrate nearly a twofold increased risk of developing T2DM irrespective of other metabolic risk factors [6, 7]. This risk intensifies with worsening hepatic involvement, and global data indicate that NAFLD affects between 34% and 94% of patients with T2DM. Although liver biopsy continues to serve as the reference method for staging fibrosis, its invasiveness, sampling variability, and procedural risks limit its feasibility for routine evaluation [8]. Consequently, diverse non-invasive biomarkers and imaging modalities have been developed to estimate the degree of hepatic fibrosis.

Elastographic techniques have become indispensable tools for non-invasive quantification of liver stiffness. Several technologies are currently in use, including transient elastography, shear wave elastography, supersonic shear wave elastography, real-time elastography, and magnetic resonance elastography (MRE). Transient elastography and shear wave elastography (SWE) are commonly adopted in clinical practice due to their broad availability, whereas MRE, though superior in diagnostic precision, remains limited by its high cost and restricted access [9, 10].

Since approximately 70% of individuals with T2DM also exhibit NAFLD — forming a fundamental component of the metabolic syndrome — early detection and intervention are critical to prevent progression to cirrhosis. The increasing prevalence of NAFLD and the variability in performance of 2D-SWE have heightened interest in reliable, non-invasive diagnostic methods. SWE, in particular, is advantageous because it is affordable, safe, operator-independent, provides real-time imaging, and allows flexible placement of the region of interest, thereby improving the accuracy of liver stiffness assessment and fibrosis monitoring [10, 11]. These observations form the rationale for the present investigation.

The **purpose of the study** was to assess the diagnostic accuracy of shear wave elastography for staging liver fibrosis in patients with diabetes mellitus and non-alcoholic fatty liver disease.

Materials and methods

A total of 140 patients with type 2 diabetes mellitus accompanied by chronic liver pathologies, who had undergone examination or treatment between 2017

and 2022 at the Educational-Surgical and Educational-Therapeutic Clinics of Azerbaijan Medical University and at the M. Mirgasimov Republican Clinical Hospital, were included in the study. The control group consisted of 30 individuals without hepatic steatosis. The inclusion criteria were as follows: age between 25 and 76 years; absence of viral hepatitis; no hereditary, dystrophic, or metabolic liver disorders; no general somatic or infectious diseases; and no history of smoking or alcohol consumption.

During the study, the stage of fibrosis was studied using ultrasound elastometry in the main group of patients, which included patients with non-alcoholic fatty liver disease (steatosis) (n=40) and diabetic patients without steatosis (n=50). The patients in the group were divided into 4 subgroups according to the degree of fibrosis. In this group of patients, liver fibrosis and its stages were determined using two-dimensional transverse (elastic) wave elastography (2D-SWE), and the effect of non-alcoholic fatty steatosis on the results of elastometry was evaluated. In order to clarify the possibilities of ultrasound examination in chronic diffuse diseases of the liver, additional B-mode examination, color and energy Doppler mapping, and pulsed-wave Doppler scanning were also performed in all patients. The number, age and gender composition of the degrees of fibrosis obtained on the basis of elastometry are shown in Table 1.

Table 1

Characteristics of patients with steatosis who underwent elastometry

Degrees of steatosis	Gender	Age	Mean age
S1 (n=14)	6 (15.0%) /8 (20.0%)	35–50	42.6 ± 6.5
S2 (n=18)	8 (20.0%)/10 (25.0%)	43–59	50.5 ± 7.8
S3 (n=8)	2 (5.0%)/6 (15.0%)	48-65	55.6 ± 8.6

Ultrasound examination was performed on an empty stomach, with the patient lying in the standard supine position and the right arm placed behind the head. The transducer was positioned longitudinally in the intercostal space at a 90° angle to the liver capsule. The color elastographic window was placed under visual control at a depth of at least 1.5–2.0 cm from the capsule, in a vessel-free area of segments VI and VII of the right hepatic lobe. Such placement of the color window helps avoid reverberation artifacts beneath Glisson's capsule and pulsation waves generated around large hepatic vessels. The elasticity range used in the study was 0–30 kPa. The control volume was positioned in the central part of the elastogram, taking the ultrasound wave propagation axis as a reference.

To quantify elasticity, a series of 5 high-quality (3–5 stable, full-color) elastograms was used. The control volume size (KH, Q-Box) was in the range of 16-18 mm and was performed in areas of interest of the same size. The use of a dual-screen mode (B-mode + 2D-SWE), in our opinion, significantly simplifies the task of locating the control volume size in the maximally homogeneous zone of the liver parenchyma. At the end of the examination, the mean value of elasticity obtained from the series of measurements (Emean) was determined.

Based on the results of transverse wave elastography examination conducted in the main group, thresholds for liver parenchymal stiffness indicators were determined to determine different degrees of fibrosis — F0-F1, F2, F3 and F4 according to METAVIR. The effect of non-alcoholic fatty liver disease on the results of elastometry in determining fibrosis was studied.

Statistical analysis of the obtained results was carried out based on the assessment of diagnostic accuracy. Correlation analysis (Spearman) and ROC analysis was performed to obtain the thresholds of stiffness indicators. The results of diagnostic accuracy were presented as sensitivity (Se), specificity (Sp), negative predictive value (NPV) and positive predictive value (PPV). The statistical packages SPSS version 20.0.5 and Statistica version 6.0 were used for statistical analysis.

Results and their discussion

The results of ultrasound elastography, which showed the relationship between liver stiffness indicators and fibrosis severity, are presented in Table 2. The obtained data showed that with the increase in fibrosis severity from F1 to F4, a continuous stepwise increase in parenchymal Me stiffness was observed. There was no significant difference between the F0 and F1 subgroups ($p > 0.05$).

Table 2

Results of SWE in patients with nonalcoholic steatosis

Indicators	Subgroups according to the stage of fibrosis (according to METAVIR)					
	F0 (n=0)	F1 (n=10)	F0+F1 (n=10)	F2 (n=13)	F3 (n=9)	F4 (n=8)
Median stiffness (Me)	-	9.95	9.95	13.9	14	22
95% confidence interval (95% CI)	-	6.8-13.0	6.8-13.0	7.2-16.1	10.6-20.7	19.4-54.8

Note: The significance of the difference between subgroups F0+F1 and F2 is $p < 0.05$; the significance of the difference between subgroups F2 and F3 is $p < 0.05$; the significance of the difference between subgroups F3 and F4 is $p < 0.05$.

Liver stiffness indices differed significantly between the remaining subgroups (p<0.05). This relationship is clearly demonstrated in the diagram, which is manifested by an increase in Young's modulus in the form of a characteristic «median step» from the combined F0+F1 subgroup to the F4 subgroup.

In this group of patients, ROC analysis allowed us to obtain the thresholds of stiffness indicators. The most optimal variant of the diagnostic efficiency of the stages of fibrosis according to METAVIR is achieved at the following stiffness indicators: for F2 > 6.8 kPa (sensitivity — 85.7%, specificity — 52.9%, AUROC — 0.684); for F3 > 8.5 kPa (sensitivity — 91%, specificity — 57.1%, AUROC — 0.745); for F4 > 14 kPa (sensitivity — 95.7%, specificity — 52.2%, AUROC -0.791). As can be seen, the stiffness indicators we obtained during the study were higher than the stiffness indicators at which the diagnostic efficiency according to METAVIR was most optimal.

A comparison was made between diabetic patients with non-alcoholic steatosis of the liver in the main group and patients in the control group (k) without steatosis and fibrosis, as well as with a small number of patients with F0+kF1 fibrosis. Since the stages of fibrosis kF2, kF3, kF4 were not found in the control group, it was not possible to compare these stages. Based on the median stiffness (kMe) obtained from the combined kF0+kF1 control group patients, it was determined that the presence of fatty changes in the liver significantly increases the stiffness of the liver tissue. Thus, in the combined control group (kF0+kF1) patients, the median liver stiffness (kMe) was found to be lower than in the corresponding subgroup of the main group (F0+F1): in the control group -kMe=6.65 kPa (95% Cl 5.6-9.5), in the main group — Me=9.95 (95% Cl 6.8-13.0) (p < 0.05, AUROC = 0.741).

The results obtained during elastometry were comparable with those obtained from morphological studies and are reflected. The Young's modulus of each stage differed significantly from the previous stage (p < 0.05). When conducting a correlation analysis between the stiffness of the liver parenchyma and the morphological stage of fibrosis, a strong correlation was found: at p < 0.001, the Spearman correlation coefficient was 0.81. Thus, the obtained Young's modulus values correlate with the stages of the METAVIR scale. The availability of morphologically verified data on the METAVIR scale allowed us to perform a ROC analysis that could determine the thresholds of liver stiffness in order to distinguish different stages of fibrosis. The data obtained at this time are presented in Table 3 and Figures 1-5.

Table 3.

Liver stiffness thresholds for diagnosing different stages of liver fibrosis according to the METAVIR scale

METAVIR stage	Stiffness, kPa	Area under the curve (AUC)	Standard error	95% confidence interval
≥ F2	7.5	0.915	0.036	0.845–0.985
≥ F3	13.25	0.932	0.031	0.871–0.992
F4	14.90	0.930	0.028	0.876–0.985

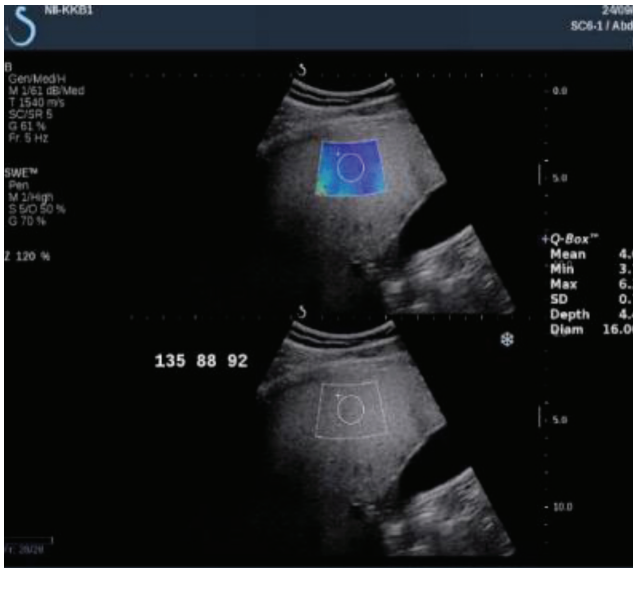

Figure 1. Two-dimensional SWE to assess liver stiffness. Result of Young's modulus measurement. F0 stage

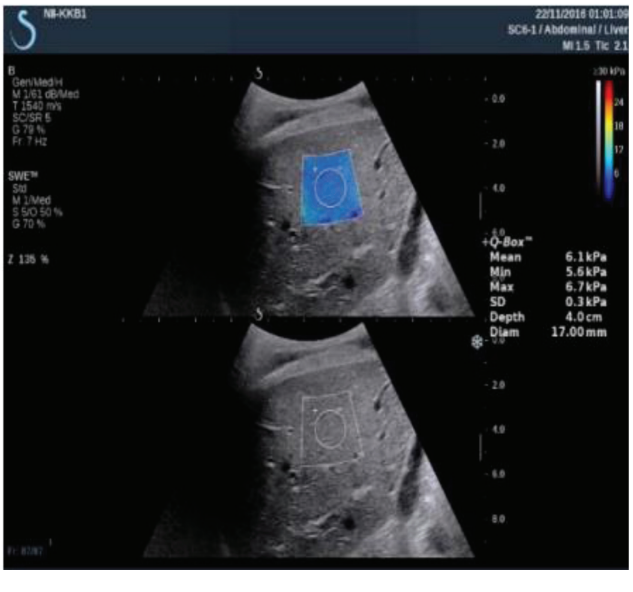

Figure 2. Two-dimensional SWE to assess liver stiffness. Result of Young's modulus measurement. Stage F1

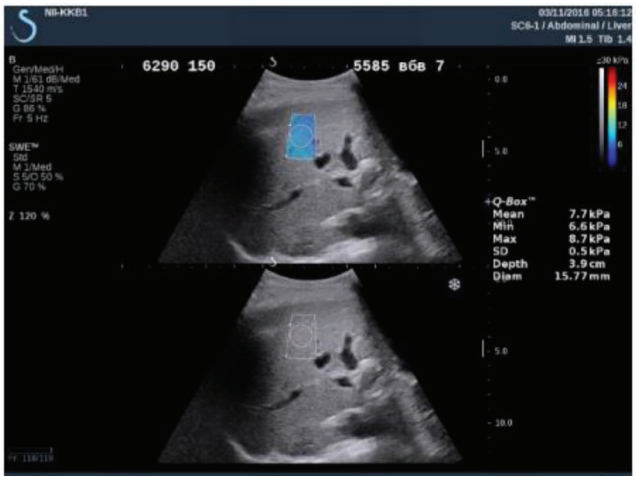

Figure 3. Two-dimensional SWE to assess liver stiffness. Result of Young's modulus measurement. Stage F2

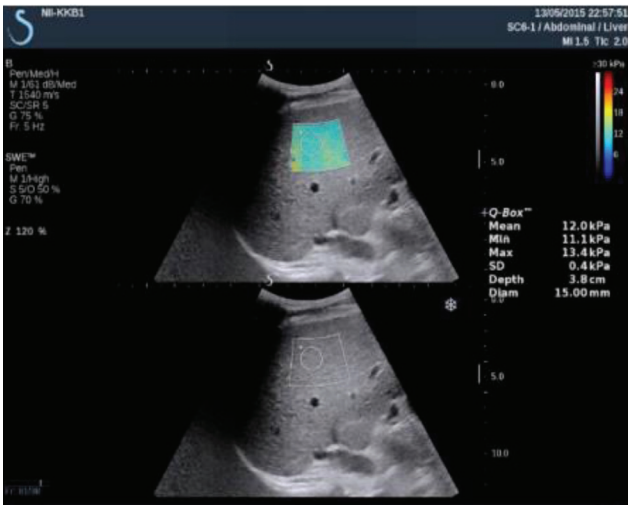

Figure 4. Two-dimensional SWE to assess liver stiffness. Result of Young's modulus measurement. Stage F3

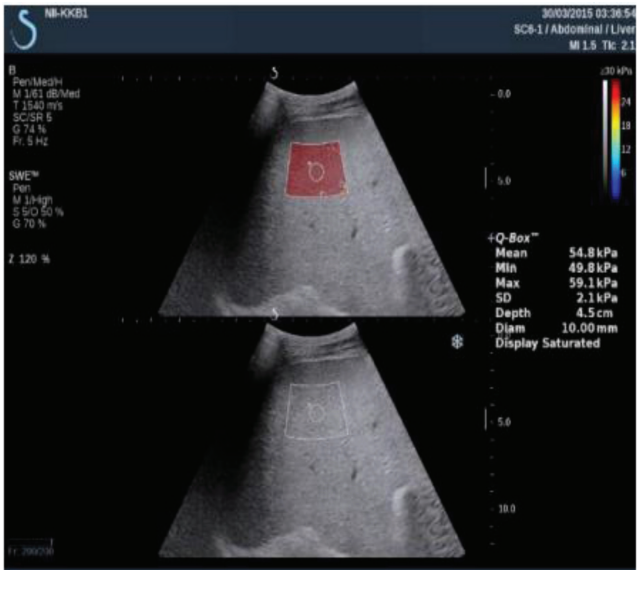

Figure 5. Two-dimensional SWE to assess liver stiffness. Result of Young's modulus measurement. Stage F4

Based on the data obtained, the quality of the examination was determined to be high: the area under the curve (AUC) in the diagnosis of fibrosis stages (F2, F3 and F4) by METAVIR two-dimensional SWE significantly differed from 0.500, which can be considered as the highest informative indicator of the diagnostic method.

By analyzing the obtained ROC-analysis data, in particular the stiffness indicators in the studied group of patients, we were able to obtain cut-off values for the stages of fibrosis according to METAVIR.

Stage F2 according to METAVIR (≥ F2). If the examination is approached from the point of view of maximum sensitivity and specificity (max (Sensitivity + Specificity) = 1.745), the cut-off value should be 7.50 kPa (sensitivity — 97.1%, specificity — 77.4%). If the requirements for the balance of the two indicators are taken into account, (min (Sensitivity — Specificity) = 0.013), then the cut-off value will be 11.15 kPa (sensitivity — 82.6%, specificity — 83.9%). Our example should be approached from the perspective of maximum sensitivity and specificity of the test: then the Young's modulus threshold for the clinically significant stage of fibrosis is 7.50 kPa, and the sensitivity and specificity of the test are 97.1 and 77.4%, respectively.

F3 stage on METAVIR (≥ F3). If the examination is approached from the point of view of maximum sensitivity and specificity (max (Sensitivity + Specificity) = 1.808), the threshold value should be 13.25 kPa (sensitivity — 88.3%, specificity — 92.5%). If the requirements for the balance of the two indicators are taken into account, (min (Sensitivity — Specificity) = 0.017), then the threshold value will be 12.5 kPa (sensitivity — 88.3%, specificity — 90%). In cases where the sensitivities are the same, it is necessary to approach the examination from the point of view of the greatest specificity requirement: if the sensitivity is 88.3%, it is 92.5%, and the threshold value of the Young's modulus is 13.25 kPa.

F4 stage on METAVIR. If the examination is approached from the point of view of maximum sensitivity and specificity (max (Sensitivity + Specificity) = 1.847), the cut-off value should be 14.90 kPa (sensitivity — 95.6%, specificity — 89.1%). If the requirements for the balance of the two indicators are taken into account, (min (Sensitivity — Specificity) = 0.002), then the cut-off value will be 15.35 kPa (sensitivity — 88.9%, specificity — 89.1%). In cases where the specificities are the same, it is necessary to approach the requirement for the greatest sensitivity of the examination: if the specificity is 89.1%, the sensitivity is 95.6%, and the cut-off value of the Young's modulus is 14.90 kPa.

Thus, our study clearly demonstrates an increase in liver stiffness in diabetic patients with hepatic steatosis ($p < 0.05$). In the F0 + F1 subgroup, this increase was 49.6%. Our study has proven that SWE is a sufficiently informative method for determining the stages of liver fibrosis. This non-invasive examination can be used to adequately assess clinically significant fibrosis in patients with steatosis. The Young's modulus value in the diagnosis of clinically significant fibrosis is 7.50 kPa.

Discussion

Type 2 diabetes mellitus and non-alcoholic fatty liver disease commonly occur together due to shared metabolic risk factors such as obesity and metabolic syndrome. The presence of T2DM accelerates the progression of NAFLD, increasing the likelihood of cirrhosis and hepatocellular carcinoma. Therefore, early identification of liver fibrosis is essential for preventing advanced hepatic complications. Two-dimensional shear wave elastography has recently been recognized as a reliable non-invasive modality for quantifying liver stiffness, reducing the necessity for liver biopsy and supporting timely therapeutic decision-making [2, 10].

Some studies demonstrated a notable prevalence of elevated liver stiffness among individuals with T2DM and NAFLD, with stiffness values showing strong associations with more advanced steatosis, higher HbA1c levels, impaired glycemic control, and adverse lipid profiles. 2D SWE proves to be an effective non-invasive tool for evaluating the degree of fibrosis and for guiding clinical management strategies in patients with NAFLD and T2DM [6, 7].

Selvaraj EA, et al (2021) noted that vibration-controlled transient elastography (VCTE), point shear wave elastography (pSWE), 2-dimensional shear wave elastography (2DSWE), magnetic resonance elastography (MRE), and magnetic resonance imaging (MRI) have been proposed as non-invasive tests for patients with non-alcoholic fatty liver disease. They evaluated their diagnostic accuracy for liver fibrosis and non-alcoholic steatohepatitis (NASH). By analyzing PubMED/MEDLINE, EMBASE and the Cochrane Library materials (in total 82 studies (14,609 patients) the authors independently screened and assessed methodological quality of studies and extracted data. According to results of meta-analysis the researchers concluded that when elastography index tests are acquired successfully, they have acceptable diagnostic accuracy for advanced fibrosis and cirrhosis [11]. These are concomitant with our results.

Jiang H, et al (2025) aimed to evaluate the feasibility of shear wave elastography for assessing the grade of liver steatosis in early-stage NAFLD without fibrosis. A total of 260 subjects were categorized into four groups, conventional ultrasound and point SWE examinations were used to assess the grade of liver steatosis in varies degrees. SWE demonstrated high reproducibility across all groups with interclass correlation coefficients ranging from 0.80 to 0.94. In addition, SWE showed better diagnostic performance than conventional ultrasound. The authors noted that SWE is a reliable tool for assessing the grade of liver steatosis, which could be a valuable tool for monitoring and grading NAFLD in early-stage [12]. We also obtained positive results related to diagnostic accuracy of SWE in staging of NAFLD.

Conclusion

Our study has proven that SWE-elastography is a sufficiently informative method for determining the stages of liver fibrosis. This non-invasive examination can be used to adequately assess clinically significant fibrosis in patients with steatosis.

Thus, elastography-based imaging techniques have the potential to substantially enhance both the screening and diagnostic evaluation of NAFLD in individuals with diabetes, thereby supporting more effective disease management. As new pharmacological agents and therapeutic strategies for NAFLD continue to emerge, their development should rely on accurate, non-invasive, and reproducible assessment tools capable of identifying disease severity in high-risk populations and guiding clinical decisions in patients with concurrent diabetes and NAFLD.

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Діагностична точність зсувнохвильової еластографії для стадіювання фіброзу печінки у пацієнтів з діабетом та НАЖХП

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Мета. Оцінити діагностичну точність зсувнохвильової еластографії для стадіювання фіброзу печінки у пацієнтів з цукровим діабетом та неалкогольною жировою хворобою печінки.

Матеріали та методи. Загалом 140 пацієнтів з цукровим діабетом 2 типу, що супроводжується хронічними патологіями печінки, які пройшли обстеження або лікування між 2017 і 2022 роками. Контрольну групу склали 30 осіб без стеатозу печінки. Під час дослідження стадію фіброзу вивчали за допомогою ультразвукової еластометрії в основній групі пацієнтів, до якої входили пацієнти з неалкогольним стеатозом печінки (n=40) та пацієнти з діабетом без стеатозу (n=50). Пацієнти групи були розділені на 4 підгрупи за ступенем фіброзу. У цій групі пацієнтів фіброз печінки та його стадії визначалися за допомогою двовимірної ультразвукової еластографії (SWE), а також оцінювався вплив неалкогольного жирового стеатозу на результати еластометрії. На основі результатів дослідження поперечнохвильовою еластографією, проведеного в основній групі, були визначені порогові значення показників жорсткості паренхіми печінки для визначення різних ступенів фіброзу — F0-F1, F2, F3 та F4 згідно з METAVIR.

Результати. Наше дослідження демонструє збільшення жорсткості печінки у пацієнтів з діабетом та стеатозом печінки ($p < 0,05$). У підгрупі F0 + F1 це збільшення становило 49,6%. Наше дослідження довело, що поперечнохвильова ультразвукова еластографія є достатньо інформативним методом для визначення стадій фіброзу печінки. Це неінвазивне дослідження може бути використане для адекватної оцінки клінічно значущого фіброзу у пацієнтів зі стеатозом. Значення модуля Юнга при діагностиці клінічно значущого фіброзу становить 7,50 кПа.

Висновок. Таким чином, методи візуалізації на основі еластографії мають потенціал для суттєвого покращення як скринінгу, так і діагностичної оцінки НАЖХП у осіб з діабетом, тим самим сприяючи більш ефективному лікуванню захворювання. Оскільки нові фармакологічні засоби та терапевтичні стратегії для НАЖХП продовжують з'являтися, їх розробка повинна спиратися на точні, неінвазивні та відтворювані інструменти оцінки, здатні визначати тяжкість захворювання у групах високого ризику та спрямовувати клінічні рішення у пацієнтів з супутнім діабетом та НАЖХП.

Ключові слова: неалкогольна жирова хвороба печінки, ультразвукове дослідження, еластометрія з частковою хвилею, діагностична цінність методу, специфічність, чутливість.

Dıagnostıc accuracy of shear wave elastography for stagıng liver fıbrosıs ın dıabetıc patıents wıth NAFLD

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Aim. To assess the diagnostic accuracy of shear wave elastography for staging liver fibrosis in patients with diabetes mellitus and non-alcoholic fatty liver disease.

Materials and methods. A total of 140 patients with type 2 diabetes mellitus accompanied by chronic liver pathologies, who had undergone examination or treatment between 2017 and 2022. The control group consisted of 30 individuals without hepatic steatosis. During the study, the stage of fibrosis was studied using ultrasound

elastometry in the main group of patients, which included patients with non-alcoholic steatosis of the liver (n=40) and diabetic patients without steatosis (n=50). The patients in the group were divided into 4 subgroups according to the degree of fibrosis. In this group of patients, liver fibrosis and its stages were determined using two-dimensional SWE elastography, and the effect of non-alcoholic fatty steatosis on the results of elastometry was evaluated. Based on the results of transverse wave elastography examination conducted in the main group, thresholds for liver parenchymal stiffness indicators were determined to determine different degrees of fibrosis – F0-F1, F2, F3 and F4 according to METAVIR.

Results. Our study demonstrates an increase in liver stiffness in diabetic patients with hepatic steatosis ($p < 0.05$). In the F0 + F1 subgroup, this increase was 49.6%. Our study has proven that transverse wave ultrasound elastography is a sufficiently informative method for determining the stages of liver fibrosis. This non-invasive examination can be used to adequately assess clinically significant fibrosis in patients with steatosis. The Young's modulus value in the diagnosis of clinically significant fibrosis is 7.50 kPa

Conclusion. Thus, elastography-based imaging techniques have the potential to substantially enhance both the screening and diagnostic evaluation of NAFLD in individuals with diabetes, thereby supporting more effective disease management. As new pharmacological agents and therapeutic strategies for NAFLD continue to emerge, their development should rely on accurate, non-invasive, and reproducible assessment tools capable of identifying disease severity in high-risk populations and guiding clinical decisions in patients with concurrent diabetes and NAFLD.

Key words: nonalcoholic fatty liver disease, ultrasound, share wave elastometry, diagnostic value of the method, specificity, sensitivity.

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