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Research Article

Evaluation of Metabolic Dysfunction-Associated Steatotic Liver Disease in Patients with Type 2 Diabetes Mellitus

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Aim: Diabetes mellitus (DM) is associated with the development and progression of metabolic dysfunction-associated steatotic liver disease (MASLD). In our study, we aimed to evaluate the findings of MASLD and fibrosis according to liver ultrasound (USG) imaging, FIB-4 score and fibroscan findings in patients with type 2 DM followed in our internal medicine clinic.

Methods: In our retrospective and cross-sectional study, 1282 patients diagnosed with type 2 DM whose anamnesis and previous examinations did not constitute an obstacle for inclusion in the study were included. The abdominal USG imaging of the patients were analysed from the system and the FIB-4 score was calculated. Liver stiffness (LS) measurements were performed with FibroScan® Mini 430 device (Echosens, France).

Results: USG imaging was performed in 474 (36.9%) of 1282 patients and MASLD was diagnosed in 341 (71.9%) of these patients. FIB-4 score≥ was 1.3 in 45 of 341 patients diagnosed with MASLD. Fibroscan imaging was performed in 231 of 341 patients with MASLD. In 52 (22.5%) of 231 patients, LS measurements≥ were 8 kPa

Conclusion: We recommend early screening of MASLD, which is associated with advanced fibrosis and increased cardiovascular mortality and morbidity in patients with DM, with liver USG, measurement of FIB-4 score and evaluation of LS with fibroscan in centres where possible.

Keywords: Diabetes mellitus, Fibroscan, FIB-4, MASLD, USG

1. INTRODUCTION

Diabetes mellitus (DM) is a chronic, metabolic disease characterised by high blood glucose levels. According to data from the International Diabetes Federation, it is estimated that approximately 700 million people will suffer from type 2 DM in 2045[1]. DM may cause damage to the eyes, kidneys, blood vessels and nerves. The liver is also an organ associated with DM as it has an important role in glucose homeostasis. Non-alcoholic fatty liver disease (NAFLD), recently renamed as metabolic dysfunction-associated fatty liver disease (MAFLD) or metabolic dysfunction-associated steatotic liver disease (MASLD), is the most common chronic liver disease worldwide[2]. MASLD is defined by the presence of at least 1 of 3 criteria including DM, obesity or two or more evidence of metabolic dysfunction in addition to the presence of hepatic steatosis. Thus, unlike NAFLD, which is a diagnosis of exclusion, the diagnosis of MASLD does not require the exclusion of excessive alcohol consumption or other chronic liver diseases[3].

Recent datas indicate that nearly one-third of the general adult population is afflicted, rendering it one of the most prevalent non-communicable illnesses[4]. Its growth and progression are closely associated with metabolic disorders and insulin resistance. Consequently, its frequency is elevated, attaining 60-75% among individuals with type 2 diabetes mellitus[5]. Research indicates a robust bidirectional

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association between MASLD and DM. MASLD elevates the risk of developing DM and the likelihood of micro- and macro-vascular complications in individuals with a history of DM; conversely, patients with diabetes often experience a more rapid progression to metabolic dysfunction-associated steatohepatitis (MASH), advanced liver fibrosis, cirrhosis, and hepatocellular carcinoma[6,7].

Biopsy is the most definitive diagnostic method for detecting and grading tissue damage in the liver. However, it is an invasive procedure with risks such as bleeding and infection. All DM patients with liver fat content >5% as determined by radiological imaging methods or biopsy are considered to have MASLD. Given the limitations of risk scoring and the invasive nature of liver biopsy, imaging is considered the main method for the diagnosis of MASLD. Due to its low cost, widespread availability and overall safety, liver ultrasound (USG) has become the guideline-recommended first-line modality for screening and diagnosis of MASLD. The fibrosis-4 (FIB-4) index, which is one of the simple scoring systems, is recommended to exclude significant or advanced liver fibrosis in patients with MASLD[8]. Considering the prevalence of the disease in the community, fibroscan has been developed as a noninvasive method for the detection of liver fibrosis and is one of the USG elastography methods. Studies have shown that fibroscan has a high performance in the diagnosis of fibrosis in patients with MASLD[9].

Despite the prevalence of MASLD in DM patients and its important extrahepatic complications, it is thought that it is often overlooked, under-recognised and under-screened in clinical practice. Increasing the awareness of clinicians about the risk and clinical significance of MASLD in patients with DM may lead to early diagnosis and timely intervention of MASLD, and the disease may be reversible. In our study, we aimed to evaluate the findings of MASLD and fibrosis according to USG imaging, FIB-4 score and fibroscan findings in patients with type 2 DM followed up in our internal medicine clinic.

2. MATERIAL AND METHOD

2.1. Study population and laboratory measurements

Our retrospective and cross-sectional study included 1282 patients with type 2 diabetes mellitus whose medical history and previous examinations did not constitute an obstacle to their inclusion in the study. Patients between 01.02.2024 and 31.12.2024 were included in the study. Diabetes mellitus was defined as fasting blood sugar level ≥126 mg/dL or HbA1c level ≥6.5% or treatment with antidiabetic medication[10]. In patients with acute-chronic liver diseases, malignancies, type 1 diabetes mellitus, pregnant women were excluded from the study. The study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional ethics committee. Adana City Training and Research Hospital Ethics Committee approved the study with decision number 319 dated 02.01.2025. After 5 minutes of rest, in a dim and quiet environment, blood pressure measurements were taken from both arms using a suitable cuff and pulses were monitored. Anthropometric body weight measurements were performed. Height was measured with the feet bare and together, leaning perpendicular to the height measurement ruler. BMI was calculated as body weight (kg) divided by the square of height in meters (BMI=kg/m2). Laboratory procedures of the study were performed in the Biochemistry Laboratory of Adana City Training and Research Hospital. Laboratory results from the date of abdominal USG were used. Venous blood was drawn from the antecubital vein after at least 8 hours of overnight fasting from the patients and the control group during routine controls. Laboratory measurements of participants were measured using automated laboratory methods (Abbott Aeroset, Minneapolis, MN) and appropriate commercial kits (Abbott). The FIB-4 score is calculated using the formula: (Age × AST) / [Platelet count × (ALT)^(1/2)].

2.2. Liver ultrasonography and liver stiffness measurements

All patients had liver ultrasound screening utilising a high-resolution USG device (Philips EPIQ 7) with a 1- to 5-MHz high-

resolution convex probe (Philips Health Care, Bothell, WA). A liver ultrasound was conducted following a minimum fasting period of 8 hours, utilising B-mode ultrasound in greyscale to evaluate liver dimensions and parenchymal echogenicity. Hepatosteatosis was evaluated. Participants were assessed separately by two seasoned radiologists. Ultrasound operators have 10 years or more of experience.

LS measurements were performed with the FibroScan® Mini 430 device (Echosens, France). Subjects were evaluated independently by two experienced internal medicine specialist. FibroScan was considered successful only when at least 10 valid readings were obtained and the interquartile range (IQR)-to-median ratio of the 10 readings was ≤.3. Participants' LS levels were determined in kPa units. LS>8 kPa was defined as a marker of significant liver fibrosis used in this study.

2.3. Statistical analysis

All analyses were performed using the statistical software package SPSS 24.0 (Chicago, IL, USA). The Kolmogorov-Smirnov test was used to assess whether the distribution of continuous variables was normal. Continuous variables in group data were expressed as mean ± standard deviation. Categorical variables were expressed as numbers and percentages. Statistical significance level was accepted as $p<0.05$.

3. RESULTS

The mean age of the patients was 59.4±7.38 years. The mean HbA1c was 6.70±1.81 and the mean duration of diabetes was 6.79±5.67 years. ±Mean AST was 25.9±13.0, mean ALT was 28.4±12.4, and mean platelet count was 232.9±68.2. USG imaging was performed in 474 (36.9%) of 1282 patients and MASLD was diagnosed in 341 (71.9%) of these patients. The mean FIB-4 score of 341 patients diagnosed with MASLD was 0.72±0.29 and the FIB-4 score≥ was 1.3 in 45 patients. All of these 45 patients had LS measurements≥ of 8 kPa. Fibroscan imaging was performed in 231 of 341 patients with a diagnosis of MASLD. The mean LS measurement of 231 patients was 5.73±2.45 and 52 (22.5%) patients had LS measurements≥ of 8 kPa (table 1).

Table 1.

Demographic, clinical, laboratory, ultrasonography findings and liver stiffness measurement of patients with type-2 dm

Variables	Patient with type 2 DM (n=1282)
Age (year)	59.4±7.38
Gender (M/F,n)	706/576
Systolic blood pressure (mmHg)	120.4±8.99
Diastolic blood pressure (mmHg)	65.7±6.52
Body mass index (kg/m2)	27.8±4.48
Waist circumference, cm	95.1±6.59
Basal heart rate (pulse/minute)	76.0±8.12
Fasting plasma glucose, mg/dL	107.4±41.6
HbA1c, %	6.70±1.81
Diabetes duration (year)	6.79±5.67
White blood cell (10^3/ µL)	7.38±1.74
Hemoglobin (g/dL)	13.4±1.59
Platelet (10^3/ µL)	232.9±68.2
Creatinine (mg/dL)	0.76±0.24
Sodium (mmol/L)	137.8±3.11
Potassium (mmol/L)	4.47±0.38
Aspartate aminotransferase (u/L)	25.9±13.0
Alanine aminotransferase (u/L)	28.4±12.4
Triglycerides, mg/dL	158.0±93.4
HDL cholesterol, mg/dL	44.6±10.4
LDL cholesterol, mg/dL	126.8±31.7
Cholesterol	329.5±99.0
CRP (mg/L)	1.44±0.87
USG imaging, n	474 (36.9%)
US-confirmed MAFLD diagnosis, n (n:474)	341 (71.9%)
CC liver size, cm (n:474)	14.2±2.02
Fib-4 index (n:341)	0.72±0.29
Fib-4 index≥1.3, n (n:341)	45 (13.1%)
Fibroscan imaging, n	231
Liver stiffness, kPa (n:231)	5.73±2.45
Liver stiffness≥8 (kPa), n (n:231)	52 (22.5%)

HDL: high density lipoprotein, LDL: low density lipoprotein, CRP: c reaktif protein, Fib-4: fibrosis-4, kPa: kilopascal, USG: ultrasonography, DM: diabetes mellitus.

4. DISCUSSION

The main findings of our study were that the rate of MASLD in patients with DM who underwent USG imaging was 71.9% and the rate of LS measurements≥ of 8 kPa in patients who underwent fibroscan imaging was 22.5%. These findings show that the rate of USG imaging in patients diagnosed with DM in outpatient clinics is low. Patients should be screened for microvascular complications during outpatient clinic examinations and should also be screened for MASLD.

The Cappadocia cohort study conducted with 2797 patients in Türkiye revealed a high prevalence of hepatic steatosis (60.1%) among the participants in abdominal USG examinations[11]. In another retrospective study including 10-year data (2007-2016) of 113239 individuals, the overall prevalence of NAFLD in Türkiye was found to be 48.3%. In this study, DM was shown to be an independent factor associated with NAFLD[12]. In another multicentre study on the awareness of MAFLD in patients with type 2 DM, USG examination was performed in 1731 (27.6%) of 6283 patients and MAFLD was diagnosed in 69.9% of the cases. In addition, it was reported that 24.4% of patients with MAFLD confirmed by USG had advanced fibrosis risk (FIB-4 index ≥ 1.3)[3]. In a pooled systemic review and meta-analysis of 156 studies and 1832125 patients, the prevalence rate of NAFLD in type 2 DM was 65.04% and 35.54% of these patients had clinically significant fibrosis (f2-f4)[13]. Diabetes and MASLD have analogous risk factors. These variables lead to systemic insulin resistance and elevated circulating free fatty acids, which are subsequently deposited in the liver, resulting in MASLD. The buildup of hepatic fat enhances insulin resistance in the liver, stimulates inflammatory pathways, elevates oxidative stress, and results in hepatic fibrosis[14]. In our study, we found that the rate of MASLD was 71.9% among patients with DM who had USG imaging. Our findings are compatible with other studies showing an increased frequency of MASLD in patients with DM in Türkiye. However, the rate of hepatic steatosis imaging with abdominal USG in patients with DM is unfortunately low. In our study, we found that the rate of USG imaging in patients diagnosed with DM was 36.9%. Considering the frequency of MASLD in patients with USG imaging, it is seen that a significant number of patients without imaging are missed and awareness is low. The findings suggest that MASLD is underdiagnosed in patients with DM and therefore should be screened. The first guidelines recommending general screening for NAFLD/MASLD in patients with DM were published by EASL, EASD in 2016. These guidelines recommended general screening for NAFLD/MASLD by liver USG in patients with type 2 DM. In case of steatosis, calculation of FIB-4 was recommended[15]. In the following years, with increasing data on the high prevalence of advanced fibrosis and cirrhosis in patients with DM, EASL published an update to clinical practice guidelines on non-invasive testing in 2021. The first step in this update is the calculation of FIB-4 and fibroscan should be performed if a value ≥ 1.3 is obtained. If the LS value is ≥8 kPa, the patient must be sent to a hepatologist. A lower number indicates that advanced fibrosis may be reliably excluded[16]. This method has been articulated in other recent guidelines from several worldwide hepatology and endocrinology groups. In 2023, the AASLD issued new guidelines recommending the screening for advanced fibrosis in all patients with diabetes mellitus, a disease that promotes development to cirrhosis. In accordance with the EASL recommendations, the initial stage is FIB-4. If FIB-4 is more than or equal to 1.3, a fibroscan or MR elastography is advised based on availability[17]. The 2023 recommendations released by the ADA also advocated a comparable strategy[18]. According to these assumptions, clinical practice recommendations advocate for the screening of MASLD and advanced liver fibrosis in individuals with diabetes mellitus utilising liver fibrosis scores and/or fibroscan.

MASLD correlates with an elevated risk of cirrhosis, cardiovascular disease, and malignancy. Individuals with MASLD remain asymptomatic until the onset of severe hepatic illness. The timely identification of MASLD is essential to avert disease advancement and related consequences. Liver biopsy is the definitive approach for

diagnosing MASH. Nonetheless, its invasiveness and possible consequences restrict its extensive application[19]. Non-invasive methods, such as fibroscan, have been established to identify fibrosis. Fibroscan has demonstrated high sensitivity in identifying MASLD and substantial fibrosis[20]. According to meta-analyses, fibroscan has an excellent diagnostic accuracy for the diagnosis of advanced fibrosis and cirrhosis in patients with MASLD (AUROC close to 0.90). However, fibroscan does not have as high sensitivity in detecting low fibrosis levels as in detecting high fibrosis levels[9]. In our study, we used the FIB-4 index, which is a simple non-invasive scoring test. In 341 patients with MASLD, we found 45 (13.1%) patients with FIB-4≥ 1.3, which can indicate the risk of advanced fibrosis. All of these patients had an LS value above 8. In 231 patients with MAFLD who underwent fibroscan, we found 52 (22.5%) patients with an LS≥ of 8 kPa indicating advanced fibrosis. 7 patients had a FIB-4 score below 1.3 although the LS value was above 8. Although FIB-4 score is a simple, noninvasive, good initial test, it may be insufficient to exclude advanced fibrosis. While the negative predictive value of the FIB-4 test is high in detecting fibrosis (FIB-4<1.3 excludes fibrosis with a high probability), its positive predictive value is low (FIB-4≥ 1.3 identifies fibrosis with a non-high probability). In addition, the accuracy of FIB-4 is low in young individuals[21]. Studies have reported that FIB-4 excludes advanced fibrosis in 55-60% of patients and fibroscan should be performed in the remaining 40-45%[22]. Our study was compatible with these data. The fact that the FIB-4 score was low in some patients with an LS value above 8 suggests that patients with MASLD should be evaluated with fibroscan in addition to the FIB-4 score. The lack of fibroscan imaging in most centres is an important problem. It should be aimed to increase the number of fibroscans in centres.

Previous research has emphasised a bidirectional relationship between MASLD and DM. On the one hand, MASLD is a known risk factor for the development of DM and its complications; on the other hand, DM increases the risk of progression towards MASH and advanced liver fibrosis[23]. Substantial epidemiological evidence from large studies suggests that MASLD is an independent risk factor for cardiovascular disease morbidity and mortality. Cardiovascular diseases are the leading cause of death for MASLD[24]. While individuals with type 2 DM already have an increased cardiovascular risk, cardiovascular mortality and morbidity increase with delayed diagnosis and failure to treat MASLD. Therefore, MASLD screening rates should be increased in patients with DM and effective treatment should be provided rapidly in diagnosed individuals.

FIB-4 index and fibroscan, which are noninvasive methods, can be used to evaluate LS in diabetic patients. Our findings show that MASLD is underdiagnosed in patients with DM in internal medicine clinics, clinicians' awareness should be increased about the high prevalence of MASLD and the risk of advanced fibrosis, and these patients should be subjected to USG imaging, the FIB-4 index should be used, and if possible, they should be referred to centers where fibroscan is performed. Current guidelines recommend a two-stage strategy in which the FIB-4 score is followed by an imaging technique (most commonly fibroscan). We believe that diabetes specialists should presently occupy a favourable position to actively manage patients with diabetes mellitus, not only to mitigate their risk of developing micro- and macrovascular complications but also to alleviate the disease burden linked to cirrhosis, hepatocellular carcinoma, and cardiovascular disease.

Our study had some limitations. Our study was single-centred. New studies with a larger number of patients and multicentre are needed. We used the fibroscan method for LS evaluation. Further studies can be performed using magnetic resonance elastography, another sensitive and non-invasive method. We did not classify the diabetic patients according to the duration of the disease, whether they were newly diagnosed or not and the oral antidiabetics used. Follow-up studies can be performed in this regard.

5. CONCLUSIONS

Despite the increasing prevalence of MASLD in diabetes, rates of MASLD screening and awareness are low. We recommend early screening of MASLD, which is associated with advanced liver fibrosis and increased cardiovascular mortality and morbidity in patients with DM, with liver USG, measurement of FIB-4 score and LS evaluation with fibroscan in centres where possible.

Article Information Form

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Authors Contribution

HAO, EG, DDO, FNA, BSA, BI, MCE, BBK, IA, CD, AGM, TS and HES conceived and designed the experiments, performed the experiments, analyzed the data, contributed reagents/materials/analysis tools, prepared figures and/or tables, authored or reviewed drafts of the paper, approved the final draft.

The Declaration of Conflict of Interest

The authors have no conflicts of interests to declare.

The Declaration of Ethics Committee Approval

Adana City Training and Research Hospital Ethics Committee approved the study with decision number 319 dated 02.01.2025.

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