Research Article

Prescription of resmetirom

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Non-invasive tests for resmetirom treatment fail to accurately define the target population: Evidence from a biopsy-proven MASLD cohort

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Abstract

Background and Aim: Resmetirom received conditional Food and Drug Administration (FDA) approval in 2024 for metabolic dysfunction-associated steatotic liver disease (MASLD) based on its promising liver-targeted therapy. Clinical trials required a histological diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) with F2-F3 fibrosis, excluding cirrhosis, while real-world prescribing relies on non-invasive tests (NITs). This study evaluates their efficacy in identifying the target population within a biopsy-proven Turkish MASLD cohort.

Materials and Methods: We analyzed 266 patients with biopsy-proven MASLD from the Turkish NAFLD Biobank. Inclusion required AST >17 U/L (females) or >20 U/L (males), and CAP ≥280 dB/m. Eligibility was defined by liver stiffness measurement (LSM) of 10–19.9 kPa (excluding cirrhosis or low platelet count) or a FAST score ≥0.67.

Results: Among the study population, 130 patients (48.9%) had histologically confirmed MASH with F2-F3 fibrosis. Based on LSM criteria applied to histologically eligible patients, 81 patients (62.3%) were underdiagnosed, compared to 95 patients (73.1%) when using the FAST score. Additionally, among patients who corresponded to NIT, 34 patients (41.0%) were overprescribed using LSM, while 23 patients (39.7%) were overprescribed using the FAST score. The kappa value as a measure of agreement showed poor compatibility for both LSM and FAST with liver biopsy (0.128 and 0.101, respectively). When treatment decisions were guided by either of the NITs, 44 patients (44.0%) received unnecessary prescriptions, and 74 patients (44.6%) had missed diagnoses.

Conclusion: The NITs defined for identifying the target population for resmetirom demonstrated poor performance in accurately detecting or excluding eligible patients. Therefore, performing a liver biopsy before starting resmetirom treatment will prevent unnecessary increases in cost and significantly reduce the economic burden of the treatment.

Keywords: Fibrosis; MASLD; MASH; non-invasive test; resmetirom.

Introduction

Metabolic dysfunction-associated steatotic liver disease (MASLD) is currently recognized as the most common chronic liver disease worldwide, affecting approximately 30% of the global population. Of these, 16% were reported to have metabolic dysfunction-associated steatohepatitis (MASH), while the global prevalence of MASH was estimated at 5%.[1] In Türkiye, epidemiological studies have previously reported a prevalence of up to 50%, underscoring the severity of the epidemic.[2,3] Alongside the already high prevalence, predictive studies suggest a growing burden of the disease, with MASLD- and MASH-related complications expected to increase significantly in the United States (US) by 2050.[4] Indeed, MASH has already become the second most common etiology for liver transplantation among patients without hepatocellular carcinoma (HCC), while it is the most common for those with HCC.[5] Similarly, in Türkiye, trends indicate a rising incidence of HCC in patients with MASH and alcoholic liver disease, although hepatitis B remains the most common underlying cause.[6]

Unfortunately, despite the significant burden of MASH, the only available treatment until last year was lifestyle modification aimed at weight loss, which is often challenging to maintain.[7,8] Last year, ongoing clinical trials demonstrated the beneficial effects of resmetirom, a thyroid hormone receptor beta agonist, in promoting MASH resolution and fibrosis regression. As a result, it received conditional approval in the U.S. in March 2024.[9] Interestingly, although the trial was based on the drug's histological response, the prescription criteria do not require a liver biopsy. Indeed, the prescription criteria include identifying MASH risk using non-invasive tests (NITs) after excluding cirrhosis.[10] On the other hand, the MAESTRO-NAFLD trial has already shown discrepancies between the chosen NITs and liver biopsy, leading to the exclusion of some patients, which corresponds to nearly 50%, based on biopsy results. These results indicate a probable overprescription of the drug using the current strategy.[11]

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Due to the recent introduction of the drug, there is currently no real-world data available on resmetirom. Therefore, we currently lack the information to assess the outcomes of this strategy and its economic impact. Moreover, it remains unclear whether NITs lead to over- or underprescription of the drug or if they offer a cost-effective approach to prescribing resmetirom for MASLD patients. In this study, we aimed to evaluate the efficacy and accuracy of the proposed NITs in identifying the target population within a biopsy-proven Turkish MASLD cohort.

Materials and Methods

Patients

For the analysis, data from the Turkish NAFLD Biobank were used.[12] The biobank contains demographic, biochemical, and histological data from Turkish patients diagnosed with MASLD who sought care at our tertiary center. Patients with viral hepatitis, drug-induced liver disease, autoimmune hepatitis, metabolic or genetic liver diseases, or those with significant alcohol consumption (>20 g/day for women and >30 g/day for men) were excluded from the dataset. The data collection procedures have been described in detail previously.[12,13] Patients without Fibroscan results or incomplete histological data were excluded from the analysis. MASLD was defined as the presence of hepatic steatosis alongside one or more cardiometabolic risk factors, with no significant alcohol consumption. These risk factors included a BMI ≥25 kg/m² or waist circumference >94 cm for men and >80 cm for women, fasting blood glucose ≥100 mg/dL or two-hour post-load glucose levels ≥140 mg/dL or HbA1c ≥5.7%, blood pressure levels ≥130/85 mmHg or presence of antihypertensive treatment, plasma triglycerides ≥150 mg/dL or lipid-lowering treatment, and HDL ≤40 mg/dL for men and ≤50 mg/dL for women or lipid-lowering treatment.[14]

Table 1. General characteristics of the study patients (n=266)

Parameter	
Age, years	51 (19–71)
Sex (male/female)	141 (53%) / 125 (47%)
Diabetes mellitus (yes/no)	169 (63.5%) / 97 (36.5%)
Hypertension (yes/no)	116 (43.6%) / 150 (56.4%)
Platelets x10³/µl	230 (89–543)
Body mass index (BMI), kg/m²	32.0 (23.7–48.2)
Waist circumference, cm	105 (79–141)
Hip circumference, cm	108 (85–143)
Alanine transferase, U/L	61 (13–209)
Aspartate transferase, U/L	40 (11–162)
Alkaline phosphatase, U/L	82 (11–226)
Gamma glutamyl transferase, U/L	48 (8–216)
Total bilirubin, mg/dL	0.7 (0.1–2.8)
Albumin, g/dL	4.6 (3.4–5.9)
Total cholesterol, mg/dL	200±46
Triglycerides, mg/dL	160 (31–463)
High density lipoprotein, mg/dL	45 (5.6–84)
Low density lipoprotein, mg/dL	126 (15–400)

Non-Invasive Tests

Fibroscan examinations were conducted using the Fibroscan 502 Touch device (Echosens SA, Paris, France) following the manufacturer's instructions. The procedure initially used the M probe, with the probe automatically switching to XL based on the real-time probe selection tool, which considers the skin-to-liver capsule distance. Patients were positioned in the dorsal decubitus position, and the transducer probe was placed in the intercostal space of the right liver lobe after a fasting period of at least six hours. A total of at least 10 valid measurements and an interquartile-range-to-median ratio of ≤0.3 were considered reliable. Controlled attenuation parameter (CAP) was used for estimation of hepatic steatosis, and liver stiffness measurement (LSM) for liver fibrosis.[15] Initially, patients with CAP ≥280 dB/m and ALT >17 U/L for females or >20 U/L for males were considered for analysis. In the next step, eligibility was determined by LSM between 10–19.9 kPa or FAST ≥0.67. Patients were excluded if they exhibited clinical signs of cirrhosis, portal hypertension, LSM ≥20 kPa, or platelet counts ≤140,000/µL.[10] When the conditions were met, the patients were considered eligible.

Liver Histology

The indication for liver biopsy was based on the presence of hepatic steatosis detected by any imaging method, accompanied by elevated aminotransferase levels for at least six months. Patients with hepatomegaly or splenomegaly but normal liver function tests were also eligible. Liver pathology was assessed by a single pathologist using the Steatosis, Activity, and Fibrosis (SAF) classification algorithm for histological evaluation. MASH was diagnosed if patients scored at least one point in each of the following categories: steatosis, lobular inflammation, and ballooning.[16] Fibrosis stage ≥2 was classified as significant fibrosis, while stage ≥3 was considered advanced fibrosis. The patients with MASH and F2–F3 stages of fibrosis were considered eligible for the resmetirom treatment.[10]

Ethics

This study adheres to the ethical principles for medical research outlined in the Declaration of Helsinki and was approved by the Ethics Committee of the School of Medicine at Recep Tayyip Erdogan University (protocol number: 2025/196). Given the retrospective nature of the study, the requirement for informed consent was waived.

Statistical Analysis

Categorical data are presented as frequencies and percentages. The normality of distribution was assessed using the Kolmogorov–Smirnov test. Normally distributed data are reported as mean ± standard deviation, while skewed data are presented as median (range). For the different NITs, the positive predictive value (PPV), negative predictive value (NPV), sensitivity, and specificity were calculated. The agreement with liver biopsy results was assessed using Cohen's kappa analysis. All analyses were performed using SPSS v.29 for Windows (IBM, Armonk, New York, USA).

Table 2. Histological parameters of the study patients (n=266)

Parameter	
Steatosis (S1/S2/S3)	43 (16.2%)/85 (32%)/138 (51.9%)
Activity (A1/A2/A3/A4)	15 (5.6%)/64 (24.1%)/95 (35.7%) /92 (34.6%)
Fibrosis (F0/F1/F2/F3/F4)	34 (12.8%)/82 (30.8%)/61 (22.9%) /72 (27.1%)/17 (6.4%)
Significant fibrosis (F≥2)	150 (56.4%)
Advanced fibrosis (F≥3)	89 (33.5%)
Cirrhosis	17 (6.4%)
MASH	133 (50%)
MASH+F2-F3	130 (48.9%)

MASH: Metabolic dysfunction-associated steatohepatitis.

Results

A total of 266 patients with biopsy-confirmed MASLD were included in the analysis (median age: 51 years [range: 19–71]; 53% male, n=141). General characteristics, including biochemical parameters, are summarized in Table 1. More than half of the patients had histologically confirmed significant fibrosis (56.4%, n=150), while 33.5% (n=89) had advanced fibrosis. Additionally, 50% (n=133) were diagnosed with MASH based on the SAF algorithm. Histologically, 48.9% (n=130) met the eligibility for resmetirom treatment criteria, presenting with MASH and fibrosis stages F2–F3 (Table 2).

In the first step, patients with CAP ≥280 dB/m and sex-adapted transaminases were assessed, with 85% (n=226) deemed eligible for the second step. When using LSM as the second step after excluding cirrhosis, 83 patients (31.2%) qualified for resmetirom, whereas the FAST score identified 58 patients (21.8%) as eligible. Based on LSM criteria applied to histologically eligible patients, 81 patients (62.3%) were underdiagnosed, compared to 95 patients (73.1%) when using the FAST score. Additionally, among patients who corresponded to NIT, 34 patients (41.0%) were overprescribed using LSM, while 23 patients (39.7%) were overprescribed using the FAST score (Fig. 1). Furthermore, we analyzed a scenario in which the physician would prescribe resmetirom if either of the two diagnostic strategies supported treatment. In this scenario, 100 patients (38.0%) were deemed eligible. Among these, 44 patients (44.0%) were overprescribed. Of the 166 patients who were not identified as eligible for resmetirom, 74 (44.6%) received missed diagnoses.

When evaluating the diagnostic performance of NITs, the sensitivity and specificity of LSM were 58% and 52%, respectively, while for FAST, they were both 54%. For either of the algorithms, the sensitivity and specificity were 43% and 68%, respectively. Overall, Cohen's kappa statistic indicated a poor level of agreement, with values of 0.128, 0.101, and 0.108, respectively (Table 3).

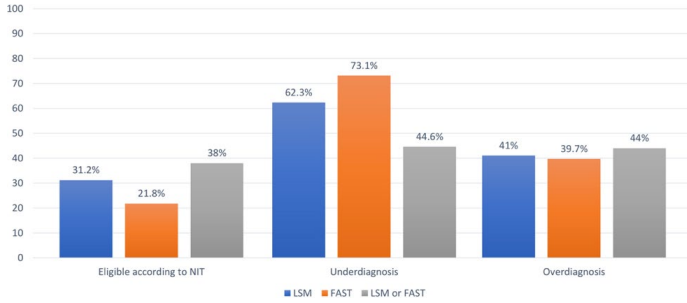

Figure 1. Comparison of diagnostic performances of algorithms including LSM and FAST.

Discussion

In this study, we demonstrated a high inaccuracy rate between NITs and liver biopsy in prescribing resmetirom. More than half of histologically eligible patients were underprescribed, while 40% of patients deemed eligible by NITs did not meet the histological criteria. Overall, the poor level of agreement highlights a significant discrepancy between NITs and liver biopsy. To the best of our knowledge, this is the first real-world study with biopsy-proven MASLD to assess the accuracy of NITs in prescribing resmetirom. Moreover, our study highlights the financial burden on the Turkish health insurance system, which appears to be exacerbated by overprescription, particularly when considering only NITs. On the other hand, more than half of the patients who were not prescribed resmetirom based on NITs actually had an indication for treatment and were labeled as missed diagnoses. This also suggests that many patients were unable to access the medication despite having a valid indication. These results indicate that a liver biopsy may be necessary before initiating resmetirom in order to identify the appropriate patients for treatment. Our findings may aid in future prescription planning for MASH patients.

Until recently, lifestyle modifications aimed at achieving a 5–10% weight loss were the only therapeutic option for MASLD.[17,18] The introduction of resmetirom specifically for MASLD has opened up new horizons, driven by the growing understanding of the disease.[11] However, the monthly cost of $1,500 for resmetirom may place a significant burden on the healthcare system. Therefore, the decision to prescribe it should be critically assessed.[19] The initiation of resmetirom was estimated to cost $348,432 over a patient's lifetime, compared to $281,668 for those receiving a placebo. Conversely, failure to treat the disease could escalate healthcare costs as it pro-

Table 3. Performance of strategies to detect the MASH+F2-F3

Parameter	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Kappa
CAP+LSM	58%	52%	0.543	0.557	0.128
CAP+FAST	54%	54%	0.543	0.543	0.101
Either CAP+LSM or CAP+FAST	43%	68%	0.560	0.554	0.108

MASH: Metabolic dysfunction-associated steatohepatitis; CAP: Controlled attenuation parameter; LSM: Liver stiffness measurement; FAST: Fibroscan-aspartate transaminase.

gresses to cirrhosis and, in some cases, necessitates liver transplantation. Indeed, cost-effectiveness analysis has shown that resmetirom could reduce the lifetime number of cases of decompensated cirrhosis (-87), hepatocellular carcinoma (-59), and liver transplants (-30) per 1,000 patients compared to placebo, increasing quality-adjusted life-years by 1.24. Therefore, the inclusion of resmetirom in the local healthcare agenda could prove to be both efficient and cost-effective.[19] On the other hand, our study revealed a significant discrepancy between liver biopsy and NITs. Therefore, the findings of such studies should be interpreted with caution. Relying solely on NITs may fail to accurately identify the target population, potentially reducing the drug's overall effectiveness.

Another ongoing challenge in healthcare planning is accurately estimating the population eligible for resmetirom. An analysis of the NHANES 2017 to March 2020 cycle, which included 4.6% MASH patients, estimated that between 1,255 and 1,699 individuals would be eligible for resmetirom treatment following its approval.[20] Using the same NHANES cohort, the estimation analysis revealed that applying NITs could identify between 2.3 to 8.3 million individuals as eligible for resmetirom. This substantial difference underscores the impact of selected NIT criteria and highlights the importance of cut-off selection Kaya et al.[21] In our study, liver biopsy findings indicated that approximately half of the MASLD population met the eligibility criteria for resmetirom. In contrast, NIT-based criteria identified 20–30% of patients as eligible. Previous population studies have estimated that nearly half of the Turkish population may have MASLD.[3] According to the latest data from the Turkish Statistical Institute, out of 60 million adult individuals, considering the real-world data with 30% prevalence, approximately 18 million are likely to have MASLD.[1] Among them, an estimated 3.6 to 5.4 million would meet the eligibility criteria for resmetirom.[12] However, nearly half of these individuals could be overprescribed the treatment. Given this high prevalence, widespread prescription of resmetirom could significantly increase the burden on the healthcare system. As a result, healthcare authorities are expected to critically assess and evaluate its indication in Türkiye. Notably, the actual prevalence in this region is estimated at around 40%, and may reach up to 50% in Turkiye.[22] As such, this approach represents the most favorable scenario in terms of minimizing economic burden.

The strength of this study lies in its large patient cohort with histologically proven MASLD, derived from the Turkish NAFLD Biobank. As a result, the study represents the Turkish population with MASLD and corresponds to the group in whom resmetirom would potentially be considered. On the other hand, besides LSM and the FAST score, other diagnostic modalities—such as ELF, magnetic resonance elastography, MAST, and MEFIB—have also been proposed for initiating treatment with resmetirom,[10] though these were not investigated in our study. The performance of other NITs has yet to be established. Furthermore, studies involving other ethnic backgrounds are also needed.

Conclusion

In conclusion, our study is the first real-world analysis to demonstrate that two of the proposed NITs lack adequate diagnostic performance. Given the high cost of the medication, prescribing resmetirom without a liver biopsy does not appear to be cost-effective. If approved in Türkiye, liver biopsy should remain a mandatory requirement for initiating treatment.

Ethics Committee Approval: This study adheres to the ethical principles for medical research outlined in the Declaration of Helsinki and was approved by the Ethics Committee of the School of Medicine at Recep Tayyip Erdogan University (date: 24.04.2025, number: 2025/196).

Informed Consent: Given the retrospective nature of the study, the requirement for informed consent was waived.

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