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Real-World Characteristics and Clinical Effectiveness Outcomes Among Patients with MASH Initiating Resmetirom

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RESONANCE Real-World Evidence of Resmetirom Advancing Outcomes, Natural History, Assessment, and Clinical Effectiveness

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INTRODUCTION

- Metabolic dysfunction-associated steatohepatitis (MASH) is a progressive liver disease characterized by hepatic fat accumulation, inflammation, and fibrosis, with the potential to progress to cirrhosis and hepatocellular carcinoma (HCC).
- On March 14, 2024, resmetirom became the first FDA-approved treatment for MASH,[1] following the MAESTRO-NASH trial, which evaluated treatment response using liver biopsy.[2]
- In clinical practice, treatment response is typically assessed using noninvasive tests (NITs); however, evidence on resmetirom use and outcomes in real-world settings remains limited.
- **Aim:** To characterize adults initiating resmetirom in routine US clinical practice and evaluate changes in liver-related measures over 12 months.

METHODS

Study Design and Methods

- Retrospective cohort study using deidentified electronic medical record (EMR) data from the Methodist Dallas Medical Center EMR systems.
- Adults aged ≥18 years with a MASH diagnosis who initiated resmetirom between March 14, 2024, and January 21, 2026, were included; patients were excluded if they had evidence of prior resmetirom use, incomplete medical records, advanced liver disease, alcohol use, or another known cause of liver disease.
- Paired t-tests and Wilcoxon signed-rank tests were used to assess mean and median changes, respectively, from baseline; percent change was calculated at the patient level.

Measures

- Labs and NITs at 12 months (±90 days) were compared with baseline values among patients with available measurements. VCTE measures (CAP and LSM) were manually extracted from clinical notes.
- Prespecified response thresholds were ALT ≥20% or ≥17 U/L, CAP ≥40 dB/m, and LSM ≥25% or ≥30% decrease.

RESULTS

Population

- Among 444 adults initiating resmetirom, mean age was 60.2 years; 41.9% were aged ≥65 years and 59.9% were female.
- Mean BMI was 32.8 kg/m²; 61.5% had obesity and 43.2% had prior GLP-1 RA use (**Table 1**).
- Cardiometabolic comorbidities were common: hypertension (75.9%), hyperlipidemia (73.9%), type 2 diabetes (64.4%), and cardiovascular disease (26.4%).

Drug Response and fibrosis

- At 12 months, 31.4% of qualifying patients had a ≥40 dB/m decrease in CAP, 37.1% a ≥25% decrease in LSM, 51.5% a ≥20% decrease in ALT, and 30.5% a ≥17 U/L decrease in ALT (**Figure 1**).
- Based on LSM change, 83.3% of patients improved or were stable and 16.7% worsened at 12 months (**Figure 2**).

Figure 1. Patients achieving response thresholds at 12 months

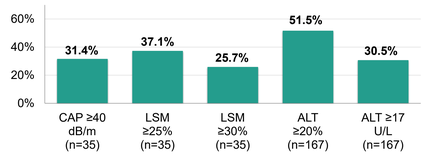


Table 1. Patient characteristics at index

Characteristic, n (%) unless specified	Study population N = 444
Age, mean (SD), years	60.20 (12.55)
Age ≥65 years	186 (41.9)
Female	266 (59.9)
White	205 (46.2)
BMI, mean (SD), kg/m²	32.8 (6.6)
Obesity (BMI ≥30 kg/m²)	273 (61.5)
Cardiovascular disease	117 (26.4)
Hypertension	337 (75.9)
Hyperlipidemia	328 (73.9)
Type 2 diabetes	286 (64.4)
Prior GLP-1 RA use	192 (43.2)
Baseline liver tests, median (IQR)*	
ALT, U/L	36.0 (25.0, 63.0)
AST, U/L	33.0 (23.0, 50.0)
CAP, dB/m	311.0 (274.0, 340.0)
LSM, kPa	9.60 (7.90, 12.20)

Comorbidities and prior treatments within 1 year before index. *Among patients tested within 1 year before index (study population n: ALT/AST 431; CAP 309; LSM 316).

Table 2. Lab and NIT measures at baseline and 12 months among patients with paired values

Measure	Baseline Mean (SD)	12-mo Mean (SD)	Baseline Median (IQR)	12-mo Median (IQR)
ALT, U/L	50.5 (39.8)	34.7 (21.7)	38 (27, 58)	30 (22, 40.5)
AST, U/L	41.7 (27)	31.4 (15.3)	34 (25, 47.5)	27 (22, 37)
CAP, dB/m	307 (48)	285.6 (59.7)	318 (275, 343)	288 (265, 324)
LSM, kPa	9.5 (2.3)	7.9 (2.5)	9.4 (8, 10.9)	7.8 (5.8, 10.2)

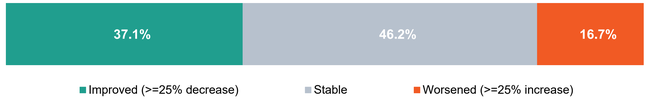
Number of patients with available measurements: ALT/AST 167; CAP/LSM 35.

Table 3. Change from baseline to 12 months among patients with paired values

Measure	n	Mean Δ (SD)	Mean % Δ	p*	Median Δ (IQR)	Median % Δ	p†
ALT, U/L	167	**-15.7 (38.2)**	**-11.8%**	<0.001	**-8 (-23,3.5)**	**-22.2%**	<0.001
AST, U/L	167	**-10.3 (27.6)**	**-6.7%**	<0.001	**-4 (-16,4)**	**-11.4%**	<0.001
CAP, dB/m	35	**-21.4 (71.5)**	**-5.0%**	0.085	**-16 (-58.5,31.5)**	**-5.0%**	0.141
LSM, kPa	35	**-1.6 (2.6)**	**-15.1%**	<0.001	**-1.4 (-2.9,-0.1)**	**-17.2%**	<0.001

*Paired t-test. †Wilcoxon signed-rank test. % Δ = mean and median of each patient's percent change from baseline.

Figure 2. Most patients improved or remained stable on LSM by 12 months (n=35)



Stable = LSM change between a 25% decrease and a 25% increase.

REFERENCES

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CONCLUSIONS

- **Liver Response in routine care:** Among patients with follow-up testing, clinically meaningful reductions at 12 months were observed in liver fat (CAP, 31.4%), liver stiffness (LSM, 37.1%), and liver injury (ALT, 51.5%).
- **Fibrosis improved or stabilized:** Among patients with paired LSM measurements, a marker of liver fibrosis, 83.3% had improved (37.1%) or stable (46.2%) liver stiffness at 12 months, while only 16.7% worsened; with a median decrease in LSM of 17.2% at 12 months.
- **Methodological Contribution:** Use of clinical note data from Methodist Dallas Medical Center's EMR enabled assessment of changes in hepatic steatosis and stiffness among patients initiating resmetirom in routine clinical practice.
- **Limitations:** This descriptive study did not include a comparator group, and follow-up NIT testing was limited and conducted at variable timepoints in routine clinical practice.

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Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; CAP, controlled attenuation parameter; EMR, electronic medical record; GLP-1, glucagon-like peptide-1; FDA, US Food and Drug Administration; HCC, hepatocellular carcinoma; IQR, interquartile range; LSM, liver stiffness measurement; MASH, metabolic dysfunction-associated steatohepatitis; NIT, noninvasive test; RA, receptor agonist; SD, standard deviation; VCTE, vibration-controlled transient elastography

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Disclosures: G. Felber, T. McKinley, C. Parrinello, and F. Lobo: employees of Madrigal Pharmaceuticals, Inc. S. Clark: consultant with Medicus Economics, LLC. P. Mantry: consultant for multiple pharmaceutical companies.