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Real-World Characteristics, Treatment Patterns, and Clinical 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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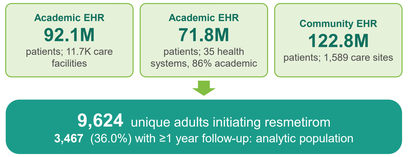
INTRODUCTION

- Metabolic dysfunction-associated steatohepatitis (MASH) is a progressive liver disease in which excess liver fat causes inflammation and scarring (fibrosis) that can lead to cirrhosis and hepatocellular carcinoma (HCC).
- Resmetirom became the first FDA-approved MASH therapy on March 14, 2024,[1] based on the MAESTRO-NASH trial, which assessed response by liver biopsy.[2]
- In routine care, response is monitored with noninvasive tests (NITs), and real-world data remain limited.
- **Aim:** to describe adults initiating resmetirom in routine US care and changes in hepatic and cardiometabolic biomarkers over 12 months.

METHODS

- Retrospective cohort study using deidentified electronic medical record (EMR) data from three Trio Health data assets, combined so each patient is counted once (Figure 1).
- Adults ≥18 years with a first resmetirom prescription (index) from March 14, 2024 to January 21, 2026, ≥1 year of prior EMR data, and regular healthcare engagement. Excluded: prior resmetirom use, missing age or sex, competing or advanced liver disease. Analytic population: patients with ≥1 year of follow-up after index.
- Labs and NITs at 12 months (±90 days) were compared with baseline. VCTE results (CAP, LSM) were extracted from clinical notes using Trio's large language model (LLM) based verifiable language inference (VLI).
- **Statistics:** paired t-tests (mean change) and Wilcoxon signed-rank tests (median change) among patients with baseline and 12-month values; % change calculated per patient.
- **Improvement thresholds:** prespecified as ALT ≥20% or ≥17 U/L, CAP ≥40 dB/m, and LSM ≥25% or ≥30% decrease. LSM change: improved (≥25% decrease), worsened (≥25% increase), or stable. Fibrosis stage (F0–F4) from F-scores in clinical notes.

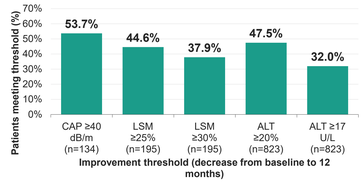
Figure 1. Patient selection: three Trio Health EHR data assets combined to identify adults initiating resmetirom



RESULTS

- **Who:** 3,467 initiators with ≥1 year of follow-up (mean age 59.1 years; 61.0% female; mean BMI 34.6 kg/m²). Hypertension (63.4%), hyperlipidemia (49.8%), and type 2 diabetes (46.8%) were common (Table 1).
- **Biomarker changes:** at 12 months, 53.7% had a ≥40 dB/m decrease in CAP, 44.6% a ≥25% decrease in LSM, and 47.5% a ≥20% decrease in ALT (Figure 2).
- **Fibrosis:** by LSM, 44.6% improved, 43.6% were stable, and 11.8% worsened at 12 months (Figure 3). By F-score, 43.8% improved ≥1 stage (Figure 4). FIB-4 did not change.
- **Lipids:** mean LDL-C decreased by 15.5 mg/dL (10.5%) and triglycerides by 34.3 mg/dL (16.2%) at 12 months (both p<0.001; Table 2). Of patients with baseline LDL-C ≥100 mg/dL (n=100), 62.0% were below 100 mg/dL at 12 months.

Figure 2. Patients with a ≥40 dB/m CAP, ≥25% or ≥30% LSM, or ≥20% or ≥17 U/L ALT decrease from baseline to 12 months after resmetirom initiation



% of patients with a value at baseline and 12 months.

Table 1. Demographics, comorbidities, and treatments in the year before resmetirom initiation, adults with ≥1 year of follow-up (N=3,467)

Characteristic, n (%) unless specified	Analytic population N = 3,467
Age, mean (SD), years	59.1 (12.4)
Age ≥65 years	1,303 (37.6)
Female	2,114 (61.0)
White	2,386 (68.8)
South region	1,352 (39.0)
BMI, mean (SD), kg/m²*	34.6 (6.5)
MASH/NASH diagnosis coded	1,438 (41.5)
Hypertension	2,197 (63.4)
Hyperlipidemia	1,728 (49.8)
Type 2 diabetes	1,621 (46.8)
Prior GLP-1 RA use	958 (27.6)
Prior statin use	1,200 (34.6)

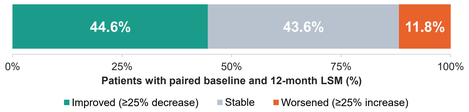
Comorbidities and prior treatments within 1 year before index. *BMI recorded for 58.2%.

Table 2. Liver tests and lipids at baseline and 12 months after resmetirom initiation, and change, in patients with both values

Measure	n	Baseline mean	12-mo mean	Mean Δ (SD)	p*	Median Δ (IQR)	p†	Mean % Δ
Liver								
ALT, U/L	823	56.5	43.0	−13.5 (43.4)	<0.001	−7 (−23, 4)	<0.001	**−6.2**
AST, U/L	782	43.5	36.2	−7.3 (28.9)	<0.001	−3 (−15, 5)	<0.001	**−2.2**
CAP, dB/m	134	319.8	271.8	−48.0 (52.7)	<0.001	−44 (−81, −19)	<0.001	**−14.0**
LSM, kPa	195	9.6	7.9	−1.7 (5.4)	<0.001	−1.7 (−4.0, 0)	<0.001	**−8.2**
FIB-4	573	1.6	1.5	0.0 (0.8)	0.748	0.0 (−0.3, 0.2)	0.217	**+5.0**
Lipids								
Total cholesterol, mg/dL	417	169.0	150.3	−18.6 (38.7)	<0.001	−16 (−36, 3)	<0.001	**−9.1**
LDL-C, mg/dL	339	93.9	78.4	−15.5 (32.6)	<0.001	−14 (−30, 4)	<0.001	**−10.5**
HDL-C, mg/dL	360	44.7	46.1	+1.4 (9.1)	0.004	1 (−4, 6)	0.002	**+5.4**
Triglycerides, mg/dL	402	176.7	142.4	−34.3 (90.5)	<0.001	−31 (−67, −2)	<0.001	**−16.2**

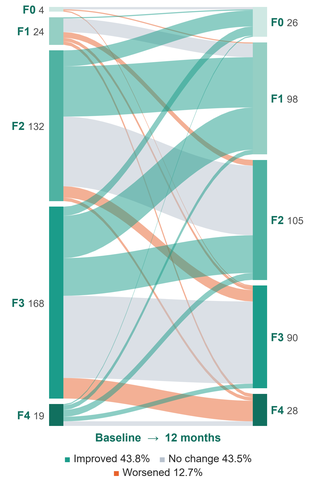
*Paired t-test (mean change). †Wilcoxon signed-rank test (median change). Mean % Δ = mean of each patient's percent change from baseline. 12 months = 9 to 15 months after index.

Figure 3. Patients whose liver stiffness (VCTE LSM) improved (≥25% decrease), stayed stable, or worsened (≥25% increase) from baseline to 12 months after resmetirom initiation (n=195)



Stable = LSM change between a 25% decrease and a 25% increase. Figures 3 and 4 differ because they use different measures and patients: VCTE LSM (n=195) vs F-scores in clinical notes (n=347).

Figure 4. Fibrosis stage (F-score in notes) at baseline vs 12 months after resmetirom initiation (n=347)



F-scores documented in clinical notes; patients with a score at baseline and 12 months (10.0% of the analytic population).

REFERENCES

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CONCLUSIONS

- **Liver biomarkers:** in routine care, about half of patients initiating resmetirom who had follow-up testing showed meaningful reductions in liver fat (CAP, 53.7%), stiffness (LSM, 44.6%), and injury (ALT, 47.5%) at 12 months.
- **Liver stiffness:** 88.2% of patients with paired LSM (a marker of fibrosis) improved (44.6%) or remained stable (43.6%) at 12 months; 11.8% worsened.
- **Fibrosis stage:** F-scores documented in clinical notes were consistent with these findings; 87.3% improved or maintained their F-score, and 20.2% improved by ≥2 stages (Figure 4).
- **Lipid profile:** at 12 months, mean LDL-C decreased by 15.5 mg/dL (10.5%) and triglycerides by 34.3 mg/dL (16.2%) (both p<0.001). This was smaller than in MAESTRO-NASH (13.7%–19.5%),[2] possibly reflecting lower baseline LDL-C (mean 2.43 vs ~2.66–2.76 mmol/L).
- **Methodological contribution:** Trio's LLM-based VLI captured VCTE results from clinical notes across three combined data assets, data that structured fields alone would miss. This made it possible to measure the steatosis and stiffness improvements above in patients initiating resmetirom in routine care.
- **Limitations:** single-arm, descriptive design without a comparator; follow-up NIT testing was limited and varies in routine care; paired analyses include only patients tested at both time points.

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Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; CAP, controlled attenuation parameter; EHR/EMR, electronic health/medical record; FDA, US Food and Drug Administration; FIB-4, fibrosis-4 index; GLP-1 RA, glucagon-like peptide-1 receptor agonist; HCC, hepatocellular carcinoma; HDL-C/LDL-C, high/low-density lipoprotein cholesterol; IQR, interquartile range; LLM, large language model; LSM, liver stiffness measurement; MASH, metabolic dysfunction-associated steatohepatitis; NASH, nonalcoholic steatohepatitis; NIT, noninvasive test; SD, standard deviation; VCTE, vibration-controlled transient elastography; VLI, verifiable language inference.

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